

U.S. Environmental Protection Agency
Science Advisory Board
Multimedia Multipathway Multireceptor Risk Assessment (3MRA)
Modeling System Panel

Final Minutes of Public Conference Call Meeting July 21, 2003

Committee: Multimedia Multipathway Multireceptor Risk Assessment (3MRA) Modeling System Panel of the U.S. Environmental Protection Agency's Science Advisory Board (SAB). (See attached Roster)

Date and Time: July 21, 2003 from 1-4 Eastern Time (See attached Federal Register Notice)

Location: Science Advisory Board, Room 6450Z, Ariel Rios North, 1200 Pennsylvania Ave, Washington D.C.

Purpose: The purpose of the conference call was to allow the Panel to plan its review.

Materials Available: The agenda, roster, Federal Register Notices for the widecast and for this conference call, the biosketches for the short list, and the public comment from SOCMA were circulated in advance of the meeting.

Attendees: All panelists attended the conference call. A full list of participants is attached to the minutes. There were about fifty people on the call including the panel, Agency staff from OEI, ORD and OSW, and members of the public.

Summary

The major elements decided at this meeting were:

1. Four volumes, the users guide and model have been sent to the DFO for distribution to the Panel
2. The Panel will hold a second conference call August 15 from 10 a.m. to noon Eastern Time to revisit the charge questions and make writing assignments by charge questions for work to be done before the first face-to-face meeting.
3. The Panel will meet August 26-27 in DC Metro area.
4. The Panel will hold a conference call meeting Tuesday September 16 3-5 Eastern
5. The Panel will hold a fourth conference call Thursday October 9 from 1 to 4 Eastern
6. The Panel will meet October 28-30 in DC Metro area.
7. The Panel will hold its fifth and probably final conference call Monday November 24 from 1-4 Eastern Time.
8. Panelists will request prior peer reviews through the DFO and the Agency will make anything available to the panel available to the public.

The following summary provides more detail on these items.

At 1:00, SAB DFO Kathleen White opened the meeting. She called the roll of the Panel, expected Agency staff, and the public. All Panelist were present, although Dr.

Stubblefield had to leave at 2:00 p.m. The list of attendees is attached. She made the following points:

1. Welcome to the conference call, which is the first in a series of face-to-face and conference call meetings at which a specially formed panel of the EPA Science Advisory Board will review the 3MRA Modeling System.
2. The activities of the Science Advisory Board are governed by the Federal Advisory Committee Act, other government regulations (such as those on conflict of interest) and SAB policies.
3. In accordance with those policies, this panel was formed using a widecast (FR dated April 11), a short list was posted June 20, and, after consideration of the comments received and the review of confidential financial disclosure statements, the current panel was formed.
4. She referred those present to the SAB website (www.epa.gov/sab) for materials relating to the 3MRA review and about panel formation.
5. All panelists have completed a course on government ethics prepared especially for Special Government Employees, like themselves.
6. All materials available to the Panel will be available to the public. Individuals wishing to be on the DFO's distribution list for materials relating to this review should send an email to that effect to the DFO (white.kathleen@epa.gov) who will add them to her list.
7. The CDs with the model and review documents have just been delivered to the SAB and will be sent to the Panel this week.
8. Public comment is accepted at SAB meetings. Written public comments are encouraged, but opportunities for brief oral comments are also scheduled.
9. SOCMA has provided written public comment for this meeting on behalf of the HWIR Consortium--which is SOCMA, ACC, API, USWAG and NCASI. Jeff Gunnulfson will be providing related oral public comment. This is not shown on the agenda. Also, the agenda shows that Mr. Laniak and Mr. Kroner will be presenting the Approach to 3MRA, but this will be done by Mr. Laniak alone.
9. All consensus drafts, and I hope earlier drafts, will be available to the public.
10. As part of the SAB's routine process for insuring the quality of the reports it provides to the Agency, after the Panel is satisfied with its report, it will be sent to the Executive Committee for review before being transmitted to the Administrator.
11. Because this is a conference call, she asked that people use the mute button if they were not speaking and identify themselves before they do speak.
12. Brief opportunity for procedural questions.

At 1:15, the panel chair, Dr. Thomas Theis said that the main purposes of the conference call were to:

- a. meet one another
- b. determine the dates for the review
- c. hear from EPA staff on 3MRA history and current status
- d. discuss the charge questions
- e. hear from the public.

He noted that the review materials will be in hand shortly. After seeing them, the Panel may have additional thoughts on the charge questions.

He asked Panelists to speak briefly about themselves and what they bring to the review. This is captured in the biosketches attached to these minutes.

In terms of the timeline for the review, he would like to see it all wrapped up before the end of the calendar year. It is a large undertaking and it is important that we do a good job, but the tentative schedule, including two face-to-face meetings assumes that end. After discussion, the Panel agreed to the following dates for meetings that will be announced in the Federal Register.

1. The Panel will hold a second conference call August 15 from 10 a.m. to noon Eastern Time.
2. The Panel will meet August 26-27 in DC Metro area.
3. The Panel will hold a conference call meeting Tuesday September 16 3-5 Eastern
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At 1:55, Dr. Vanessa Vu, Director of the SAB Staff Office thanked the panelists for taking the time to contribute to this significant effort. She thanked Agency officials for their preparation for and participation in the review and also the public commenters. She apologized for the late publication of the notice for this conference call meeting and hoped that the remaining meetings will be announced in a timely way.

At 2:00 Dr. Theis noted that we were beginning the Agency presentations and turned the next section of the meeting over to Barnes Johnson, current Deputy Director, Office of Radiation and Indoor Air, formerly Director of the Economic Methods and Risk Analysis Division of the Office of Solid Waste.

Mr. Johnson said that the Panel should feel free to identify anything in their presentation of particular interest that they would like to hear about in more depth. Because of the mechanics of the conference call, he thought he would stop periodically to take questions.

Mr. Johnson managed the development of 3MRA over the last several years together with other staff the Panel will hear from on this call and subsequent calls and meetings. There are two significant drivers for the history and context of 3MRA. One is a regulatory need by OSW in the RCRA program. That need stems from the federal hazardous waste rules "mixture and derived from" rules. These rules are important from a risk management perspective. Hazardous wastes can be identified waste stream by waste stream identifying those with hazardous properties. Wastes can also be identified as hazardous through a concentration or characteristics procedure (TCLP). The "mixture and derived from" rule applies to listed wastes and says, no matter what you do to the waste, it is still hazardous. This rule has been useful in managing some wastes but over-regulates others. Therefore, the program has had an interest in identifying a risk-based rule so that wastes with less than certain risks would no longer be considered hazardous.

The second driver relates to improvement in risk assessment methods. OSW had increasing interest in multimedia, multipathway models that would allow consideration of all pathways; in looking at subpopulations of concern; in ecological

endpoints; in considering multiple chemicals in one analysis; and in uncertainty analysis. The confluence of these science issues in the regulatory program came to ahead in 1995 when OSW sought to amend the “mixture and derived from” rule. OSW brought the model associated with HWIR to the SAB for review and was told that they needed to look at total integrated exposure across all pathways and other points. These can be read in the SAB’s report *Review of a Methodology for Establishing Human Health and Ecologically Based Exit Criteria for the Hazardous Waste Identification Rule (HWIR)* (EPA-SAB-EC-96-002), which can be read at <http://www.epa.gov/sab/pdf/ec96002.pdf>

OSW and ORD have worked closely together in the development of 3MRA and have made extensive use of the Agency’s peer review and data quality programs. Now they are looking for a holistic peer review from the SAB. They would like the SAB to look at the system from the 10,000 foot level – does it hang together? does it make sense? is this a strategic approach? EPA is at the point where it needs to decide whether to continue funding tools of this type.

At 2:15, Dr. Rose Russo, Division Director of the Ecosystems Research Division within the National Exposure Research Laboratory of EPA ORD. She noted that, besides the Division in Athens, the Atmospheric Modeling Laboratory in RTP and the National Center for Exposure Assessment and the Nation Health and Environmental Research Laboratory in RTP contributed. She would like the SAB to evaluate what they have developed. Various modules reside within an open software architecture.

This system fits into an ORD objective for establishing a modeling system for broad use. ORD’s role is that of a leader to encourage good science. OSW had an immediate practical need which ORD saw as a way to move EPA towards the next generation of models – and one which can evolve as new science and data become available. ORD thinks 3MRA is a powerful tool which can be used at different stages in the regulatory development process; can be used by researchers, regulators, and stakeholders; can be used by other programs and states;

She mentioned EPA’s Council on Environmental Regulatory Modeling, chaired by Dr. Gary Foley to promote consistency and consensus among model developers and users in EPA. CREM is also working with other federal agencies (MOUs with NRC, Corps of Engineers, DOE, USGS, NASA and NOAA) to have a shared technology with a common scientific basis. And also reduce duplication and expense between agencies.

Dr. Murarka asked whether the CDs the Agency is providing contain the model itself. Gerry Laniak of Athens said yes, one of the CDs has the model and installation program allowing the panelists to use 3MRA the same way OSW has. It works in Windows 98 and 2000; they have not tried it in Windows XP but think it should work. If there are problems, ORD will provide support. Russo said that if anybody—panel or public—they should call the help numbers. Panelists will work through the DFO who will serve as a witness that no improper communication occurred with the Agency in this process.

Dr. Thibodeaux asked for clarification about “legacy models” in the context of an open architecture system. Babindreaux responded said that there are a series of black boxes that say what comes in and what comes out. If one were in a mind to replace one black box with another as long as one abides by the more system oriented data requirements, so that the module uses and produces the same types of models. Dr. Russo added that these modules had been peer reviewed and said that someone who

wanted to substitute a different model – but the user would have to provide for the relevant peer review. Dr. Carbone said EPA is not advocating individual modelers “plug and play” but that if new models become available in the future, ORD could review them and swap if they provided advantages. Babendrier said there is a need in a regulatory context to “lock in” certain models and data, but – for ORD – there is a research need to compare models. Part of ORD’s motivation was to build an architecture that would allow evaluation of various models and have the rest of the multi-media model available so you can see how your model relates to the rest of the simulation.

At 2:35 Dr. Laniak said it was a pleasure to be on the call. Some 35-40 people on the 3MRA team see this review as the last lap of a long marathon they have been running. They look forward to the recommendation of the Board.

From a management perspective, the goal was to develop national regulatory waste concentration limits for chemical wastes managed in Subtitle D units so that waste streams presenting little risks can be released from regulation. The approach needed to be:

Risk based

Human and ecological exposures and risks

Applies to any waste stream entering a land based unit

Solution applies across a variety of settings (national perspective)

The 1995 SAB review raised certain big picture items:

it was inconsistent

methods for evaluation average and high end risks questions

methods for accounting for mass questioned

uncertainty and sensitivity analysis

quality assurance

documentation was unclear, difficult to use.

In his briefing, he addressed the following areas:

1. National assessment methodology – how to develop measures of risk across the country and present
2. Collection of science models
3. Data that drives the models
4. Technology that automates
5. Quality Assurance and Validation
6. Uncertainty
7. Documentation

At 3:10 Mr. Steve Kroner went through the materials will be available to the Panel and how the public will get access to them. OSW is working to upload the information on the web at the site identified in the Federal Register notice. If anyone is interested at this moment in receiving a CD set, they have limited numbers for the public if they contact him by email (kroner.stephen@epa.gov) or phone (703 308 0468)

Nadine Wineberg asked if any of the results would be available to the public; Kroner responded that some are in Volume 4 and others will be presented at the face-to-face meeting. Dr. Muraraka asked if the modeling would be done chemical-by-chemical or multiple at the same time. Babendrier responded that the model is built on a management unit basis (43 chemicals, 5 types of management units). The risk assessment summary is done for a chemical/management unit combination.

At 3:20 Jeff Gunnulfsen of SOCMA presented public comments for the HWIR Consortium. The Consortium consists of American Chemistry Council (ACC), American

Petroleum Institute (API), the Synthetic Organic Chemical Manufacturer's Association (SOCMA), the National Council on Air and Stream Improvement (NCASI) and Utilities Solid Waste Activities Group (USWAG). They have been following 3MRA closely since it was released in 1999 and provided public comments on the previous version. The Consortium hopes SAB will clarify a number of issues about the use of the model. They feel a detailed review of the model is needed to be sure the results represent actual conditions and have suggested additional questions that could be included in the charge. (See written comments attached)

At 3:25 the chair noted that they had about a half hour to discuss the charge. The presentations on the history and structure of the charge were excellent. He went through the charge questions (as published in the April 11, 2003 FR).

Charge Question 1: *While the EPA had the assessment methodology peer reviewed prior to the development of the 3MRA modeling system, does the SAB have any additional comments about the methodology as implemented?*

Dr. Murarka asked if, instead of looking at the changes in documentation, the Panel could look at the current documentation as a stand alone. Dr. Theis noted that Question 4 looks at progress in documentation since 1995 and asked if Murarka meant the Panel could consider just the current documentation. Barnes Johnson commented that the Agency has sought input along the way and tried to follow the direction; there is no need for a comparative analysis. Carbone read the 1995 documentation and said it would be refreshing to read a concise and current version. Eschenroeder asked if those unfamiliar with the 1995 document should read the SAB peer review. Foran asked about the availability of prior reviews.

The SAB review of a model very different from the current 3MRA is available SAB's report *Review of a Methodology for Establishing Human Health and Ecologically Based Exit Criteria for the Hazardous Waste Identification Rule (HWIR)* (EPA-SAB-EC-96-02), which can be read at <http://www.epa.gov/sab/pdf/ec96002.pdf>

In addition, between the SAB review in 1995 and the present, EPA sought additional peer review, getting more than 45 letter peer reviews along the way.

Mr. Kroner said that the other peer reviews are available, if the panel wants them. Barnes Johnson said that they could send those relating to the assessment methodology, if that would be helpful. Most of the other peer reviews look at sub elements of the model.

Eschenroeder asked for a list of the titles so that they could pick and choose.

Russo said they are asking for a look at the forest, not the tree, let alone the twigs. There's over a hundred different documents the Panel could look at, just please focus on the overall system. She doesn't think it is worth reading the SAB's review, but the points – as listed in the research plan – should be useful. The plan is at the OSW website.

Subair Saleem says that Volume 3 lists the peer reviews that were conducted and who did which reviews. Doug Smith asked whether, if they wanted to sample a couple of those documents just to reassure themselves that someone had given attention to a particular point of interest, they could have access to them. Barnes and Russo said yes, the panelists can have anything they want, but there are several hundred pages. All are available electronically.

Theis would like to steer a pathway between re-reviewing parts that have already been reviewed. But there is a tendency for many reviewers to look at the small parts and having these prior peer reviews available will reassure those panelists who like to get into the details. If there is a table of contents in Volume 3, panelists can cross reference

Agency just needs to be sure that what's available to the panel is available to the

public. Panelists will request prior peer reviews through the DFO.

No further questions on Charge Question 1

Charge Question 2a: *Does the 3MRA modeling system provide a tool for performing national risk assessments that facilitates consistent use of the science and provides a mechanism for reproducing results?*

Charge Question 2b: *Does the 3MRA modeling system provide decision-makers sufficient flexibility for understanding the impacts on potential chemical exemption levels by allowing varying measures of protection based on the number of receptors and/or number of sites protected, types of human and ecological receptors, and distance?*

Charge Question 2c: *Does the 3MRA modeling system provide appropriate information for setting national risk-based regulations for the waste program?*

No Panel questions on Charge Question 2

Charge Question 3a: *Is the software development and verification testing approach implemented for the 3MRA modeling system sufficient to ensure confidence that the modeling results reflect the modeling system design?*

Dr. Theis noted it would be hard to decide on Charge Question 3a without looking at the material.

Charge Question 3b: *Given the thorough evaluations that EPA has implemented using the available data resources and technologies, while also recognizing the real world limitations that apply to validating the 3MRA modeling system, have we reasonably demonstrated through methodology design, peer review, quality control, sensitivity analyses, and model comparison, that the 3MRA modeling system will produce scientifically sound results of high utility and acceptance with respect to multimedia regulatory applications?*

Dr. Murarka asked, if the system design has some limitations and panelists had ideas about how to remove those limitations, could the panelists provide them? Dr. Theis responded that the important thing is that the limitations be made more transparent. Dr. Murarka thought that it would be useful to suggest improvements and Theis agreed that they would be appropriate to suggest.

There were no further Panel questions on Charge Question 3

Charge Question 4: *Has the EPA made substantive progress, relative to 1995, in designing and preparing documentation for the 3MRA modeling system? Does the SAB have additional suggestions for improving the presentation of the comprehensive set of materials related to this modeling system?*

Dr. Theis thought this was fairly clear and noted it would be hard to decide on Charge Question 3a without looking at the material. Dr. DeFur thinks the question suggests a comparison. He thinks there is no need to do an historical review; the Panel should focus on the second part of the Charge Question.

Barnes Johnson said that question is worded the way it is because they got science advice from the SAB and would like to know if they have improved. We could

ask if 3MRA is OK in absolute terms, and that's fine, but they did focus where they were given advice. Rosemarie Russo doesn't think the Panel needs to go back and read the earlier information. By including Dr. Murarka who served on the 1995 HWIR review for continuity and institutional memory, that should be enough. For her part, she is more interested in the second part. Babendrier also thinks that's enough.

Ms. Boissevain says that the 1998 Research Plan lists the SAB's recommendations. It may be helpful just to look at the table of contents of the 1995 Model just to see if the content and organization had been improved. DeFur thought a responsiveness summary, if available, would be great. A document that summarizes what the SAB said and what the Agency did would be perfect. Dr. Russo said they don't have a document exactly like what journal editors get.

There were no further Panel questions on Charge Question 4

There were no further Panel questions on any of the Charge Questions.

At 3:50 Dr. Smith asked about the public comment, which Dr. Theis noted is advisory to the Panel. For obvious and practical reasons, it is very important that the Panel agree to a charge before they get deep into the work. DePinto thinks there's a lot of room for re-interpreting some of the charge questions which could cover some of the questions raised in the public comment. He suggested that, before the next call, the panelists reflect on what the charge questions really mean. Dr. Theis spoke to the need to strike a balance between the interest of the Agency in getting a high level review and addressing the details. The charge will be the main topic of discussion on August 15.

After thanking the members for their efforts, Dr. Theis adjourned the meeting at 3:55 p.m.

Respectfully Submitted:

Certified as True:

/signed/
Ms. Kathleen White
Designated Federal Official
Environmental Engineering Committee

/signed/
Dr. Thomas Theis, Chair

Attachments (electronic)

1. Agenda for the meeting
2. List of attendees
3. Committee roster
4. Federal Register Notices
5. Biosketches
6. Public Comment from SOCMA
7. July 21 email approving minutes with minor edits (paper copy)

**U.S. Environmental Protection Agency
Science Advisory Board
Executive Committee
Multimedia Multipathway Multireceptor Risk Assessment (3MRA)
Modeling System Panel
TELECONFERENCE
AGENDA
July 21, 2003
1-4 Eastern Time**

- 1:00 Mechanics of the Conference Call, Identification of Who Is on the Line, Etc.
Welcome and Opening Remarks
Ms. Kathleen White, Designated Federal Officer,
Science Advisory Board Staff Office
- 1:20 Welcoming Remarks, Purpose of Meeting, and Introduction of Panel
Dr. Thomas Theis, Chair, Multimedia Multipathway Multireceptor Risk
Assessment (3MRA) Modeling System Panel
- 1:40 SAB Staff Office Director's Remarks
Dr. Vanessa Vu, Director, Science Advisory Board Staff Office
- 1:50 Agency Presentation of Subject and Materials

History of, Rationale for, and Regulatory Context for the 3MRA Model (20 min)

Mr. Barnes Johnson current Deputy Office Director, Office of Radiation and
Indoor Air, formerly Director of the Economic Methods and Risk Analysis Division, Office
of Solid Waste

Dr. Rose Russo, Division Director of the Ecosystems Research Division within
the National Exposure Research Laboratory of ORD

Approach to 3MRA (20 min)
Mr. Gerry Laniak, Environmental Engineer, Ecosystems Research Division,
NERL
Mr. Steve Kroner, Environmental Protection Specialist, EMRAD

Materials for Review: Data, Documents, and Model:
Brief Description and Timing of Availability (20 min)
Mr. Steve Kroner, Environmental Protection Specialist, EMRAD
- 2:50 Public Comment (if Any)
- 3:00 Panel Discussion of Charge and Preliminary Planning
Dr. Theis and Panel
- 3:40 Summary of Actions and Selection of Dates for Subsequent Meetings
- 3:50 DFO's Wrap Up
- 4:00 ADJOURN

Actual Attendees at July 21, 2003 3MRA Conference Call

1. Kathleen White, DFO

Panelists

2. Dr. Thomas Theis, Director, Institute for Environmental Science and Policy, University of Illinois at Chicago, Chicago, IL
3. Dr. Randy Maddalena, Scientist, Environmental Energy Technologies Division, Indoor Environment Department, Lawrence Berkeley National Laboratory, Berkeley, CA
4. Ms. Andrea Boissevain, President, Health Risk Consultants, Inc., Fairfield, CT
5. Dr. Linfield Brown, Professor, Department of Civil and Environmental Engineering, Tufts University, Medford, MA
6. Dr. John Carbone, Senior Scientist, Environmental Toxicology and Environmental Risk Assessment, Toxicology Department, Rohm and Haas Company, Spring House, PA
7. Dr. James Carlisle, Senior Toxicologist, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, Sacramento, CA
8. Dr. Peter deFur, President, Environmental Stewardship Concepts, Richmond, VA
9. Dr. Joseph DePinto, Sr. Scientist, Limno-Tech, Inc., Ann Arbor, MI
10. Dr. Alan Eschenroeder, Faculty Member, Environmental Health, Harvard School of Public Health, Harvard University, ,
11. Dr. Jeffrey Foran, President & CEO, Citizens for a Better Environment, Milwaukee, WI
12. Dr. David Merrill, Principal, Gradient Corp., Cambridge, MA
13. Dr. Ishwar Murarka, Chief Scientist and President, ISH Inc., Sunnyvale, CA
14. Dr. Doug Smith, Principal Scientist, ENSR International, Westford, MA
15. Dr. William Stubblefield, Toxicologist, Parametrix, Corvallis, OR
16. Dr. Louis J. Thibodeaux, Jesse Coates Professor, Gordon A. & Mary Cain Department of Chemical Engineering, College of Engineering, Louisiana State University, Baton Rouge, LA
17. Dr. Curtis Travis, Scientist, Quest Technologies, Knoxville, TN

Agency

18. Office of Solid Waste
Gary Ballard, David Cozzie, Steven Kroner, Zubair Saleem
19. Office of Research and Development, Athens
Justin Babbendrier, Gerry Laniak, Candida West AND Rose Russo

20. Barnes Johnson
21. ~~ORD-HQ-Rep~~ Not present at start of call
22. Vanessa Vu
23. Garey Foley and Donna Schwede (Jewel Morris may join later)
Public - **Please include affiliation and contact information**
24. Mark Luce, ChevronTexaco Corp. (925 842 3451)
25. Mario Gamboa, American Chemistry Council (703.741.5238) and Corrinne Doyle
26. David Spanfelner, DuPont
27. Debbie Elcock, Argonne National Labs 202 488 2451
28. Neil Shah, Risk Policy Report (703 416 8578) (Not present at start of call)
29. Kristy A.N. Bulleit, Partner, Hunton & Williams LLP, ~~202/955-1547~~
Not present!
30. Bill MacNair, Air Products and Chemicals, Inc. (610) 481-5967
31. Nadine Wineberg, Arcadis 207 828 0046
32. Don Barnes 703 768 9192 (Not present at start of call)
33. Ted Steichen, API 202 652 8568
34. Russ Furnari and Tom Harklukowicz, Public Service Enterprise Group 973
430
8848
35. Dua Guvanasen, Hydrologic 703 736 4528
36. David Case, ETC 202 783 0870
37. Laura Solem and Vanessa Ranek, Minnesota Pollution Control Agency, 218 529
6254
38. Michael Gray, AMEC 207 879 4222
39. Ned Ferguson, for Battery Council Int'l 202 383 6930
40. Jeff Gunnulfsen, SOCMA, 202 721-4198
41. Annette Mold, EPA/OEI (566-0637)
42. Jeff Koss, Inside EPA (703 416 8500)
43. Stephen Beaulieu RTI 919 541 7425
44. Denis Leonart, Detroit Electric

**U.S. Environmental Protection Agency
Science Advisory Board
Executive Committee
Multimedia Multipathway Multireceptor Risk Assessment (3MRA)
Modeling System Panel***

CHAIR

Dr. Thomas Theis, Director, Institute for Environmental Science and Policy, University of Illinois at Chicago, Chicago, IL

Also Member: Environmental Engineering Committee

OTHER SAB MEMBERS

Dr. Randy Maddalena, Scientist, Environmental Energy Technologies Division, Indoor Environment Department, Lawrence Berkeley National Laboratory, Berkeley, CA

Member: Integrated Human Exposure Committee

CONSULTANTS

Ms. Andrea Boissevain, President, Health Risk Consultants, Inc., Fairfield, CT

Dr. Linfield Brown, Professor, Department of Civil and Environmental Engineering, Tufts University, Medford, MA

Dr. John Carbone, Senior Scientist, Environmental Toxicology and Environmental Risk Assessment, Toxicology Department, Rohm and Haas Company, Spring House, PA

Dr. James Carlisle, Senior Toxicologist, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, Sacramento, CA

Dr. Peter deFur, President, Environmental Stewardship Concepts, Richmond, VA

Dr. Joseph DePinto, Sr. Scientist, Limno-Tech, Inc., Ann Arbor, MI

Dr. Alan Eschenroeder, Faculty Member, Environmental Health, Harvard School of Public Health, Harvard University, Cambridge, MA

Dr. Jeffrey Foran, President & CEO, Citizens for a Better Environment, Milwaukee, WI

Mr. David Merrill, Principal, Gradient Corp., Cambridge, MA

Dr. Ishwar Murarka, Chief Scientist and President, ISH Inc., Sunnyvale, CA

Dr. Doug Smith, Principal Scientist, ENSR International, Westford, MA

Dr. William Stubblefield, Toxicologist, Parametrix, Corvallis, OR

Dr. Louis J. Thibodeaux, Jesse Coates Professor, Gordon A. & Mary Cain Department of Chemical Engineering, College of Engineering, Louisiana State University, Baton Rouge, LA

Dr. Curtis Travis, Scientist, Quest Technologies, Knoxville, TN

SCIENCE ADVISORY BOARD STAFF

Ms. Kathleen White, Designated Federal Officer, 1200 Pennsylvania Avenue, NW, Washington, DC, Phone: 202-564-4559, Fax: 202-501-0582, (white.kathleen@epa.gov)

* Members of this SAB Panel consist of

a. SAB Members: Experts appointed by the Administrator to serve on one of the SAB Standing Committees.

b. SAB Consultants: Experts appointed by the SAB Staff Director to a one-year term to serve on ad hoc Panels formed to address a particular issue.

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<http://www.epa.gov/fedreg/EPA-SAB/2003/April/Day-11/sab8951.htm>
<http://www.epa.gov/fedreg/>

[Federal Register: April 11, 2003 (Volume 68, Number 70)]
[Notices]
[Page 17797-17800]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr11ap03-49]

ENVIRONMENTAL PROTECTION AGENCY
[FRL-7481-5]

Science Advisory Board; Request for Nominations for Experts for a
Panel on Multimedia, Multipathway, and Multireceptor Risk Assessment
(3MRA) Modeling System

AGENCY: Environmental Protection Agency (EPA).
ACTION: Notice.

SUMMARY: The Environmental Protection Agency Science Advisory Board (SAB) is announcing the formation of a new panel regarding the Multimedia, Multipathway, and Multireceptor Risk Assessment (3MRA) Modeling System and soliciting nominations for membership on this panel.

DATES: Nominations should be submitted no later than May 2, 2003.

ADDRESSES: Nominations should be submitted in electronic format through the Form for Nominating Individuals to Panels of the EPA Science Advisory Board provided on the SAB Web site. The form can be found at http://www.epa.gov/sab/sab_panel_form.htm. To be considered, all nominations must include the information required on that form. Anyone who is unable to submit nominations via this form may contact Ms. Kathleen White, Designated Federal Officer (DFO), as indicated below.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information regarding this Request for Nominations may contact Ms. Kathleen White, (DFO), U.S. EPA Science Advisory Board (1400A), by telephone/voice mail at (202) 564-4559, by fax at (202) 501-0582; or via e-mail at <A

HREF="<mailto:white.kathleen@epa.gov>">white.kathleen@epa.gov.

SUPPLEMENTARY INFORMATION:

1. Summary: The Environmental Protection Agency (EPA) Science Advisory Board (SAB) is announcing the formation of a new Panel to review the technical validity of the Multimedia, Multipathway, and Multireceptor Risk Assessment (3MRA) Modeling System for setting national risk-based regulations on the waste program. The SAB is soliciting nominations to establish the members of the new Panel.

This Panel is being formed to provide advice to the Agency, as part of the EPA SAB's mission, established by 42 U.S.C. 4365, to provide independent scientific and technical advice, consultation, and recommendations to the EPA Administrator on the technical bases for EPA decision making. The Board is a chartered Federal Advisory Committee, which reports directly to the Administrator.

2. Background: There have been substantial efforts by Federal and State organizations and the private sector to develop risk assessment tools that include the evaluation of contaminants in different media

and the integration of exposures across pathways to help establish an integrated risk-based assessment.

In December 1995, EPA's Office of Solid Waste proposed to amend existing regulations for disposal of listed hazardous wastes under the Resource Conservation and Recovery Act (RCRA). The December 1995 proposal (60 FR 6634, December 21, 1995) outlined the Hazardous Waste Identification Rule (HWIR) that was designed to establish constituent-specific exit levels for low risk solid wastes that are currently captured in the RCRA subtitle C hazardous waste system. Under this proposal, waste generators of listed wastes that could meet the new concentration-based criteria defined by the HWIR methodology would no longer be subject to the hazardous waste management system specified under subtitle C of RCRA. This would have established a risk-based ``floor'' for low risk hazardous wastes that would encourage pollution prevention, waste minimization, and the development of innovative waste treatment technologies.

In May and June of 1995, EPA's Science Advisory Board (SAB) reviewed the proposed HWIR methodology for calculating exit concentrations and in May 1996 published its findings in Review of a Methodology for Establishing Human Health and Ecologically Based Exit Criteria for the Hazardous Waste Identification Rule (HWIR) (EPA-SAB-EC-96-002), available at http://www.epa.gov/sab/pdf/ec96002.pdf. In

addition to this review, EPA's Office of Research and Development (ORD), and numerous industrial and environmental stakeholders, also reviewed the proposed methodology. While the SAB concluded that the methodology ``lacks the scientific defensibility for its intended regulatory use,' ' the SAB also made the following recommendations that, when addressed, should provide an adequate scientific basis for establishing a risk-based methodology applicable at the national level for the waste program:

(a) Develop a true multi-pathway risk assessment in which a receptor receives a contaminant from a source via all pathways concurrently, is exposed to the contaminant via different routes, and accounts for the dose corresponding to each route in an integrated way;

(b) Maintain mass balance;

(c) Conduct substantial validation of the methodology and its elements, against actual data derived from either the laboratory or field, prior to implementation of the model;

(d) Conduct a systematic examination of parameters to ensure a consistent and uniform application of the proposed approach, and further, the full suite of uncertainties to be addressed for the final methodology;

(e) Discard the proposed screening procedure for selecting the initial subset of chemicals for ecological analysis and instead require that a minimum data set

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be satisfied before ecologically based exit criteria are calculated;

(f) Seek the substantive participation, input, and peer review by Agency scientists and outside peer review groups as necessary, to evaluate the individual components of the methodology in much greater detail; and,

(g) Reorganize and rewrite the documentation for both clarity and ease of use.

As a result of the methodology reviews, the Office of Solid Waste (OSW) collaborated with the Office of Research and Development (ORD) to develop and document a sound science foundation, supporting data for an assessment, and related software technology for an integrated, multimedia modeling system (entitled 3MRA) following the recommendations of the SAB and other reviewers. This effort was initiated with the peer review of an integrated research and development plan (ORD/OSW Integrated Research and Development Plan for the Hazardous Waste Identification Rule (HWIR), 1998 available at:

http://www.ep

a.gov/epaoswer/hazwaste/id/hwlrwste/risk.htm), that describes the assessment methodology, the technical bases for the integrated multimedia modeling system, and quality controls to be followed during the developmental process. The Multimedia, Multipathway, and Multireceptor Risk Assessment (3MRA) modeling system represents a collection of science-based models and databases that have been integrated into a software infrastructure that is based on the FRAMES (Framework for Risk Analysis in Multimedia Environmental Systems) concept, which provides a computer-based environment for linking environmental models and databases and managing the large amounts of information within the system, including the visualization of outputs. This integrated multimedia modeling system provides national-level estimates of human and ecological risks resulting from long-term (chronic) chemical release from land-based waste management units. Over 45 experts participated in the peer review process of the underlying science within the 3MRA modeling system.

The EPA plans to use the modeling system to help inform managers on a variety of decisions in the waste program, such as setting concentration-based exit criteria for wastes in the hazardous waste management regulations, or deciding whether technology-based standards are protective of human health and the environment.

3. Proposed Charge to the Panel: The EPA is asking the SAB to focus its review in the following four areas: assessment methodology, 3MRA modeling system, modeling system evaluation, and modeling system documentation. Charge questions related to those areas are identified in the relevant section below.

Assessment Methodology

The 3MRA assessment methodology presents a strategy for estimating national distributions of human and ecological risks resulting from long-term (chronic) chemical release from land-based waste management units. The national distribution is constructed by performing "site-based" assessments at a statistically significant number of randomly sampled hazardous waste site locations across the U.S. In the assessment methodology, a pollutant is released from a waste management unit to the various media (air, water, soil) according to its chemical properties and characteristics of the unit. The pollutant is transported through the media and exchanged between media via system linkages. Receptors are exposed concurrently to the pollutant via multiple pathways/routes resulting in an integrated dose.

The methodology describes a tiered approach for populating data files for each site evaluation. The approach is referred to as "site-based" because the assignment of data values for the site being simulated occurs according to a tiered protocol. Data values are filled first with data at a site level; when site data are not available, a statistically sampled value from a geographically relevant regional distribution of values are used; and lacking a representative regional distribution for the variable, a value from a national distribution is assigned.

The 3MRA methodology was designed specifically to include Monte Carlo simulation methods to address both uncertainty and variability in the risk outputs. Statistical distributions for many modeling parameters were developed and upon implementation provide a statistical measure of variability and uncertainty, i.e., the range and distribution of potential exposures and risks occurring at a site. When applied to the sites in a national assessment, the result is a statistical measure of variability and uncertainty, and national distributions of risks. The sites currently in the database are randomly selected from sites across the United States to represent the national variability in waste management scenarios and locations. The methodology for selecting the sites allows for measures of protection to be calculated at the site level and aggregated over all the sites to develop the national distribution of risks.

Charge Question 1: While the EPA had the assessment methodology peer reviewed prior to the development of the 3MRA modeling system, does the SAB have any additional comments about the methodology as implemented?

3MRA Modeling System

To implement the 3MRA methodology, the EPA chose to develop a comprehensive software-based modeling system, which facilitates the consistent use of sound-science models through a framework that controls model sequencing, facilitates data exchange, and provides data analysis and results visualization tools. Following modern Object Oriented software design and development principles and honoring the use of legacy models (i.e., fate and transport models that have a long history of use at the EPA), the EPA has constructed a modern modeling system that facilitates the consistent and reproducible application of the 3MRA modules and databases to problems requiring a national-scale assessment of site-based risks. The 3MRA modeling system is underpinned by a software infrastructure named FRAMES. FRAMES provides a computer-based environment for linking and applying environmental models and managing the large amounts of information within the system.

The 3MRA modeling system consists of: (a) 17 science-based modules that estimate chemical fate, transport, exposure, and risk; (b) 7 system processors that select data for model execution; manage information transfer within the system; ``roll-up'' site-based results into distributions of risk at the national level; and provide a visualization of the system outputs; and (c) multiple databases that (currently) contain the data for waste managements sites across the country as well as regional and national distributions of data values, (d) a software infrastructure (framework) based on FRAMES.

The 3MRA system was designed to provide flexibility in producing distributions of hazards or risks at sites that may manage exempted waste because the final regulatory decision framework for defining chemical-specific exit levels has not been formulated. The system is designed to allow the evaluation of human health impacts to the general population or selected subpopulations and the impact of varying the measures of protection at different probability levels. The system

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has similar capabilities with respect to evaluating the impacts on ecological systems.

Charge Question 2a: Does the 3MRA modeling system provide a tool for performing national risk assessments that facilitates consistent use of the science and provides a mechanism for reproducing results?

Charge Question 2b: Does the 3MRA modeling system provide decision-makers sufficient flexibility for understanding the impacts on potential chemical exemption levels by allowing varying measures of protection based on the number of receptors and/or number of sites protected, types of human and ecological receptors, and distance?

Charge Question 2c: Does the 3MRA modeling system provide appropriate information for setting national risk-based regulations for the waste program?

Modeling System Evaluation

In response to the SAB recommendation that substantial evaluation of the modeling system is essential to building confidence in the system, the EPA focused significant efforts to ensure the scientific integrity of the 3MRA system and its results during system development and post-development. The EPA designed and implemented rigorous quality assurance and quality control procedures for software development, data collection, verification testing, and peer review on the scientific components of the system.

The EPA implemented specific steps to build a level of confidence in the system to ensure that the system will present a reasonable estimate of nationwide risk for a national-level assessment.

First, the overall technical approach and each science-based module included in 3MRA have been peer reviewed. Teams of peer reviewers (at least three per module) provided critical feedback about the science-based modules. All told, over 45 independent experts reviewed the science modules to ensure that the theoretical concepts describing the processes within release, fate, transport, uptake, exposure, and risk

components were adequate representations of the processes to be evaluated.

Second, all software components and databases underwent a series of tests to verify that the software and data were performing properly. At the heart of this protocol is the requirement that each component of the modeling system include a designed and peer reviewed test plan that is executed by both the model developer and a completely independent modeler (i.e., someone who did not participate in the original model development). These procedures, test plans, test packages, and test results are fully documented and available to the public.

Third, a comprehensive data collection approach was developed to parameterize the modeling system in accordance with the site-based approach described in the assessment methodology. This data collection plan described the general collection methodology for the major types of data (for example, facility location, land use, soil characteristics, receptor locations), including quality assurance and quality control procedures and references for data sources. Fourth, the 3MRA modeling system has undergone a comparison analysis with EPA's Total Risk Integrated Methodology (TRIM) that is currently under development. The objective of the model comparison effort was to increase confidence that the 3MRA modeling system produces estimates consistent with other multi-media models.

While complete validation of a modeling approach would be the ultimate proof for a multimedia system like the 3MRA, the EPA did not find a multimedia data set to compare with the system's predictive outputs. In addition, the model comparison study was conducted using an actual industrial site where environmental monitoring data for mercury representing the relationship between contaminant source and environmental concentrations were available (albeit an incomplete set of observational data). Finally, a formal program focusing on sensitivity and uncertainty analysis for high-order modeling systems has been initiated at ORD. The early focus of this program is the investigation of parameter sensitivities and system uncertainties within the 3MRA modeling system. A supercomputer has been configured to allow exhaustive experimentation with the 3MRA system in Monte Carlo mode. Initial results of these efforts have been documented.

Charge Question 3a: Is the software development and verification testing approach implemented for the 3MRA modeling system sufficient to ensure confidence that the modeling results reflect the modeling system design?

Charge Question 3b: Given the thorough evaluations that EPA has implemented using the available data resources and technologies, while also recognizing the real world limitations that apply to validating the 3MRA modeling system, have we reasonably demonstrated through methodology design, peer review, quality control, sensitivity analyses, and model comparison, that the 3MRA modeling system will produce scientifically sound results of high utility and acceptance with respect to multimedia regulatory applications?

3MRA Modeling System Documentation

In response to significant comments regarding the lack of clarity and transparency associated with documentation of the earlier modeling system the EPA has devoted significant time and resources to correcting this limitation. The 3MRA represents a comprehensive risk assessment capability and as such integrates the science from all contributing disciplines. Documentation is necessarily voluminous. In preparing the current documentation our intent is to provide different levels of presentation depending on the intended audience. The EPA has prepared a significant number of reports and documents at various levels of technical complexity that describe the 3MRA modeling system and the related HWIR application.

The review documents consist of a four volume set of documents, providing a comprehensive overview of the 3MRA modeling system. These documents are intended to be the primary means by which the general public would become familiar with the 3MRA system and are also intended to provide the level of information necessary for a risk assessor to make an informed decision regarding the applicability of the 3MRA

modeling system to specific risk assessment problems.

Charge Question 4: Has the EPA made substantive progress, relative to 1995, in designing and preparing documentation for the 3MRA modeling system? Does the SAB have additional suggestions for improving the presentation of the comprehensive set of materials related to this modeling system?

4. Development Plan Document Available: For the purpose of enough understanding about the 3MRA modeling system to nominate candidates, the reader may find the ORD/OSW Integrated Research and Development Plan for the Hazardous Waste Identification Rule (HWIR), 1998 helpful. This document introduces the policy and technical issues shaping the development of the 3MRA modeling system. This document is available at:

http://www.epa.gov/epaoswer/hazwaste/id/hwirwste/risk.htm.

5. SAB Request for Nominations: Any interested person or organization may nominate qualified individuals for Membership on the Subcommittee.

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Individuals should have expertise in one or more of the following areas:

- (a) Integrated Software Technology for Multimedia Modeling
- (b) Sensitivity and Uncertainty Analyses for Higher Order Environmental Models
- (c) Quality Assurance and Model Evaluation
- (d) Integrated Multimedia Fate and Transport Modeling--air focus
- (e) Integrated Multimedia Fate and Transport Modeling--surface water focus
- (f) Integrated Multimedia Fate and Transport Modeling--groundwater focus
- (g) Integrated Multimedia Fate and Transport Modeling--food chain focus
- (h) Integrated Modeling for Human and Ecological Risk Assessments
- (i) National Probabilistic Risk Assessment using Monte Carlo-based Methods
- (j) Properties of Chemicals and Environmental Media
- (k) Nation-wide Risk Assessments
- (l) Human toxicology
- (m) Ecological toxicology
- (n) Risk Communication
- (o) Familiarity with hazardous waste regulations and remediation technologies.

6. Process and Deadline for Submitting Nominations: Any interested person or organization may nominate qualified individuals to add expertise in the above areas for the Panel. Nominations should be submitted in electronic format through the Form for Nominating Individuals to Panels of the EPA Science Advisory Board provided on the SAB Web site. The form can be found at http://www.epa.gov/sab/sab_panel_form.htm. To be considered, all nominations must include the information required on that form.

Anyone who is unable to submit nominations using this form may contact Ms. Kathleen White at the mailing address in the section above entitled, FOR FURTHER INFORMATION CONTACT. Nominations should be submitted in time to arrive no later than May 2, 2003. Any questions concerning either this process or any other aspects of the notice should be directed to Ms. White.

The EPA Science Advisory Board will acknowledge receipt of the nomination and inform nominators of the panel selected. From the nominees identified by respondents to this Federal Register notice (termed the ``Widecast''), SAB Staff will develop a smaller subset (known as the ``Short List'') for more detailed consideration. Criteria used by the SAB Staff in developing this Short List are given at the end of the following paragraph. The Short List will be posted on the SAB Web site at: http://www.epa.gov/sab.

and will include, for each candidate, the nominee's name and their biosketch. Public comments will be accepted for 21 calendar days on the Short List. During this comment period, the public will be requested to provide information, analysis or other documentation on nominees that the SAB Staff should consider in evaluating candidates for Panel.

For the EPA SAB, a balanced review panel (i.e., committee, subcommittee, or panel) is characterized by inclusion of candidates who possess the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors, can be influenced by work history and affiliation), and the collective breadth of experience to adequately address the charge. Public responses to the Short List candidates will be considered in the selection of the panel, along with information provided by candidates and information gathered by EPA SAB Staff independently on the background of each candidate (e.g., financial disclosure information and computer searches to evaluate a nominee's prior involvement with the topic under review). Specific criteria to be used in evaluating an individual subcommittee member include: (a) Scientific and/or technical expertise, knowledge, and experience (primary factors); (b) absence of financial conflicts of interest; (c) scientific credibility and impartiality; (d) availability and willingness to serve; and (e) ability to work constructively and effectively in committees.

Short List candidates will also be required to fill-out the "Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency" (EPA Form 3110-48). This confidential form, which is submitted by EPA SAB Members and Consultants, allows Government officials to determine whether there is a statutory conflict between that person's public responsibilities (which includes membership on an EPA Federal advisory committee) and private interests and activities, or the appearance of a lack of impartiality, as defined by Federal regulation. The blank form may be viewed and downloaded from the following URL address: (<http://www.epa.gov/sab/pdf/epaform3110-48.pdf>). Subcommittee members will likely be asked to attend two public face-to-face meetings and several public conference call meetings over the anticipated course of the review. The face-to-face meetings are likely to be in the July, August, September timeframe.

Dated: April 4, 2003.
Vanessa T. Vu,
Director, EPA Science Advisory Board Staff Office.
[FR Doc. 03-8951 Filed 4-10-03; 8:45 am]
BILLING CODE 6560-50-P

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EPA-SAB Digest for Wednesday, July 16, 2003.

1. Science Advisory Board; Notification of an Upcoming

Subject: Science Advisory Board; Notification of an Upcoming

From: envsubset@epamail.epa.gov

Date: Wed, 16 Jul 2003 11:25:08 -0400 (EDT)

X-Message-Number: 1

<http://www.epa.gov/fedreg/EPA-SAB/2003/July/Day-16/sab18004.htm>

<http://www.epa.gov/fedreg/>
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[Federal Register: July 16, 2003 (Volume 68, Number 136)]

[Notices]

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From the Federal Register Online via GPO Access [wais.access.gpo.gov]

[DOCID:fr16jy03-79]

ENVIRONMENTAL PROTECTION AGENCY

[FRL -7528-2]

Science Advisory Board; Notification of an Upcoming Meeting of
the Multimedia, Multipathway, and Multireceptor Risk Assessment; (3MRA)
Modeling System Panel

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory
Board Staff Office (SAB) announces an upcoming teleconference meeting
of the Multimedia, Multipathway, and Multireceptor Risk Assessment
(3MRA) Modeling System Panel at which the Panel will plan its review.

DATES: The teleconference meeting will take place on July 21, 2003 from
1 p.m. to 4 p.m. (Eastern Time).

ADDRESSES: Participation in the teleconference will be by telephone
only.

FOR FURTHER INFORMATION CONTACT: To obtain the call-in number and
access code required to participate in the teleconference, contact Ms.
Sandra Friedman, EPA Science Advisory Board Staff, at (202) 564-2526 or
via e-mail at <[A HREF="mailto:friedman.sandra@epa.gov">friedman.sandra@epa.gov](mailto:friedman.sandra@epa.gov). Those
wishing further
information about the Panel may contact Ms. Kathleen White, Designated
Federal Officer (DFO), EPA Science Advisory Board at (202) 564-4559 or
via e-mail at <[A HREF="mailto:white.kathleen@epa.gov">white.kathleen@epa.gov](mailto:white.kathleen@epa.gov). General
information concerning
the EPA Science Advisory Board can be found on the SAB Web site at:
<[A HREF="http://www.epa.gov/sab">http://www.epa.gov/sab](http://www.epa.gov/sab).

SUPPLEMENTARY INFORMATION:

Background: Pursuant to the Federal Advisory Committee Act, Public
Law 92-463, notice is hereby given that the Multimedia, Multipathway,
and Multireceptor Risk Assessment (3MRA) Modeling System Panel of the
U.S. EPA Science Advisory Board (SAB) will meet to plan its review of
EPA's Multimedia, Multipathway, and Multireceptor Risk Assessment
(3MRA) Modeling System.

The panel was charged with responding to questions concerning the modeling system. These questions were published in a Federal Register Notice on April 11, 2003 (68 FR 17797-17800). More information regarding this review can be found at the SAB Web site at http://www.epa.gov/sab/panels/3mramspanel.html. The review documents provide and background information will be made available at http://www.epa.gov/epaoswer/hazwaste/id/hwirwste/risk.htm when they become available.

Individuals who are unable to access the documents electronically may contact Mr. Stephen Kroner of the Office of Solid Waste at 703 308-0468 or via e-mail at kroner.stephen@epa.gov to make other arrangements. A very limited number of paper copies can be made available in special circumstances.

The purpose of this meeting is to allow contemporaneous public access to the Panel's introduction to the review, discussion of the charge, and preliminary organization for the review. Most of the review will be conducted at two face-to-face meetings currently planned for late August and late October, 2003. A copy of the draft agenda for the Teleconference will be posted on the SAB Web site (www.epa.gov/sab) (under the AGENDAS subheading) approximately 7 days before the meeting.

Providing Oral or Written Comments at SAB Meetings: It is the policy of the EPA Science Advisory Board (SAB) to accept written public comments of any length, and to accommodate oral public comments whenever possible. The EPA SAB expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements.

Oral Comments: In general, each individual or group requesting an oral presentation at a face-to-face meeting will be limited to a total time of ten minutes (unless otherwise indicated) and no more than one hour total for all speakers. For teleconference meetings, opportunities for oral comment will usually be limited to no more than two minutes per speaker and no more than ten minutes total for all speakers. Interested parties should contact the DFO at least one week prior to the meeting in order to be placed on the public speaker list for the meeting. Speakers may attend the meeting and provide comment up to the meeting time. Speakers should bring at least 35 copies of their comments and presentation slides for distribution to the reviewers and public at the meeting.

Written Comments: Although the SAB accepts written comments until the date of the meeting (unless otherwise stated), written comments should be received in the SAB Staff Office at least one week prior to the meeting date so that the comments may be made available to the review panel for their consideration. Comments should be supplied to the DFO at the address/contact information noted in the opening of this notice in the following formats: one hard copy with original signature, and one electronic copy via e-mail (acceptable file format: Adobe Acrobat, WordPerfect, Word, or Rich Text files (in IBM-PC/Windows 95/98 format). Those providing written comments and who attend the meeting are also asked to bring 35 copies of their comments for public distribution. Should comment be provided at the meeting and not in advance of the meeting, they should be in-hand to the DFO up to and immediately following the meeting. The SAB allows a grace period of 48 hours

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after adjournment of the public meeting to provide written comments supporting any verbal comments stated at the public meeting to be made a part of the public record.

Meeting Access: Individuals requiring special accommodation at this meeting, including wheelchair access to the conference room, should contact Ms. Sandra Friedman, sandra.friedman@epa.gov or by telephone/voice mail at (202) 564-2526 at least five business days prior to the

meeting date so that appropriate arrangements can be made.

Dated: July 9, 2003.
Vanessa T. Vu,
Director, EPA Science Advisory Board.
[FR Doc. 03-18004 Filed 7-15-03; 8:45 am]
BILLING CODE 6560-50-P

**Invitation for Comments on the "Short List" Candidates for the Panel on Multimedia, Multipathway, and
Multireceptor Risk Assessment (3MRA) Modeling System
EPA Science Advisory Board (SAB)
May 29, 2003**

The EPA Science Advisory Board (SAB) announced in 68 FR 17797-17800, April 11, 2003, that it was forming the Panel on Multimedia, Multipathway, and Multireceptor Risk Assessment (3MRA) Modeling System and requested nominations for potential panel members. Background on the project and details on panel nomination process appear in the above referenced Federal Register notice and are also available at the SAB website (www.epa.gov/sab).

The Science Advisory Board Staff Office has reviewed the nominations for the Panel, and has identified a list of nominees to a Short List of 35 candidates based on the qualifications and interest of the nominees. Brief biosketches of the candidates on the "Short List" are listed below for comment. We invite comments from the public on these candidates. We welcome information, analysis or documentation that the Board should consider in evaluating the "Short List" remaining candidates.

The SAB Staff Office Director, in consultation with SAB leadership, as appropriate, makes the final decision about who will serve on the panel in the "Panel Selection" phase. In that phase, SAB Staff completes its review of information regarding conflict of interest, possible appearance of lack of impartiality, and appropriate balance and breadth needed to address the charge. They review all the information provided by the candidates, along with any information that the public may provide in response to the posting of information about the prospective panel on the SAB website during the "Short List Phase," and information gathered by SAB Staff independently on the background of each candidate.

Please provide any advice, observations or comments you might think would be helpful in selecting the final candidates no later than June 20, 2003. Please make your comments to the attention of Ms. Kathleen White, Designated Federal Officer. E-mailing comments (white.kathleen@epa.gov) is the preferred mode of receipt. We intend to make final selections by July 3, 2002.

Andrea Boissevain

Ms. Andrea Boissevain is the Principal and Senior Scientist with Health Risk Consultants, Inc., a woman-owned environmental consulting firm in Fairfield, CT. Ms. Boissevain has extensive experience as a risk assessor with skills that range from designing exposure models to managing multi-media quantitative human health assessments for state and federal Superfund sites across the nation. After receiving her Masters in Public Health (Environmental Health Concentration) from Yale University Department of Epidemiology and Public Health in 1984, she worked with a large environmental engineering concern before starting her own firm in 1989.

Ms. Boissevain is currently developing exposure assessment methodologies to evaluate individual exposures to a variety of indoor pollutants, including volatile organic compounds. Several of the sites she is working on are grappling with exposure to soil gas vapors associated with impacted groundwater. Knowing the science, assessing the health risks, and developing outreach strategies to inform the public are daily challenges she addresses. Risk communication and making science understandable to myriad audiences now comprise a large component of her work. Her basic science background (A.B. Vassar College, Biology) and her pursuit of toxicology (graduate school and beyond) coupled with her love of writing has shaped her firm's commitment to communicating with people (clients and the public alike) about the health implications of exposures (both acute and chronic) to hazardous substances.

With respect to funding sources and contract support, HRC serves a variety of private (Fortune 100 firms, engineering and law firms) and public sector clients, most notably the Department of the Navy, US Environmental Protection Agency, the Connecticut Department of Public Health and the Town of Stratford. Ms. Boissevain is a long standing member of the Society for Risk Analysis, American Public Health Association, and the New England Society for Risk Analysis. She also served on panel of experts that employed risk-based principles to screen and prioritize over 2000 state-classified abandoned hazardous waste sites for the Virginia Department of Environmental Quality (VDEQ). A subset of sites were sampled, information collected, and a hazardous ranking scheme developed. The expert panel assembled provided professional judgment in the final priority assignments of the sites to enable VDEQ to assess state [financial] liability for cleaning up abandoned sites.

Linfield Brown

Linfield C. Brown is Professor and former Chairman of the Civil and Environmental Engineering Department at Tufts. Professor Brown earned his BSCE and MS from Tufts and his Ph.D. in Sanitary Engineering at the University of Wisconsin-Madison.

His research has covered a broad range of topics in sampling strategies, flow equalization, oxygen transfer, and most recently, uncertainty analysis in water quality modeling, multi response parameter estimation, and the use of genetic algorithms for model calibration.

Dr. Brown has served as consultant to both industry and government. As a research engineer with the National Council for Air and Stream Improvement (NCASI), he developed their national program in

mathematical water quality modeling. While on sabbatical leave at the USEPA Center for Exposure Assessment Modeling (CEAM), he designed and implemented a computational framework for incorporating uncertainty analysis into the water quality model, QUAL2E. He is the author of over 50 technical papers and reports covering the fields of environmental engineering and statistics and has offered over two dozen workshops in the US, Spain, Poland, England, and Hungary on water quality modeling and control. He is co-author of the book Statistics for Environmental Engineers, which describes the practical application of statistics to a variety of environmental engineering problems. He founded and was academic director of an innovative multi-disciplinary Masters program in Hazardous Materials Management, and initiated a similar program in Environmental Science and Management for mid-career professionals, targeted specifically for women and minorities. He received from Tufts, the prestigious Lillian Liebner Award for excellence in teaching and advising. Dr. Brown currently serves as consultant to the Environmental Models Sub-committee of the USEPA Science Advisory Board and is director of the Tufts ABET accredited BSEvE program. In addition to his university support, Dr. Brown receives funding from the New England Water Pollution Control Commission, which, in turn receives that funding from EPA Region I.

John P. Carbone, Ph.D. is currently a senior scientist within the Toxicology Department of the Rohm and Haas Co., one of the world's largest manufacturers of specialty chemicals. Dr. Carbone received his Ph.D. in endocrine physiology in 1982, his graduate research focused on PCB and PBB effects on thyroid and adrenal function. After a postdoctoral fellowship at Thomas Jefferson University Hospital, Dr Carbone joined the faculty of Thomas Jefferson University Medical school where he participated in teaching, research and grant writing. In 1991, Dr Carbone joined the Toxicology Department at the Rohm and Haas Co. His initial responsibilities included sub-chronic study director. Dr. Carbone migrated toward environmental risk assessment where during the past 11 years he has developed expertise in environmental exposure analysis, specifically fate and transport modeling of chemicals in the environment.

Dr Carbone participated in the FIFRA Environmental Modeling Task Force where he chaired the statistics subcommittee. In that committee, Dr. Carbone led the development and implementation of an uncertainty analysis approach for a multiparametric fate and transport model, PRZM. PRZM models chemical movement via runoff and movement through the vadose zone. In the approach that was developed, uncertainty associated with model parameterization was accounted for by using a sensitivity analysis coupled with a Monte Carlo approach to account for the variability associated with these inputs.

In addition, Dr. Carbone has extensive experience with a variety of both US and European fate and transport models. He also closely monitors endocrine disrupter issues and is a key advisor for the Rohm and Haas Co. regarding the European Chemicals Policy and the Water Framework Directive.

Dr. Carbone is a member of the Society for Environmental Toxicology and Chemistry and also serves on the editorial board of Environmental Toxicology and Chemistry where his expertise is in fate and transport modeling and environmental risk assessment. Dr. Carbone also works with the Alkylphenol Ethoxylates Research Council where he is an active member of the environmental subcommittee.

Dr. Carbone's work is fully supported by the Rohm and Haas Co.

James Carlisle

Senior Toxicologist, Office of Environmental Health Hazard Assessment
California Environmental Protection Agency.

Doctor of Veterinary Medicine, University of California, Davis

Master of Science in Aquatic Pathobiology, University of Stirling, Scotland

Current professional responsibilities include oversight of the:

A Emerging Environmental Challenges Program

A Environmental Indicators Program

A OEHHA California/Baja California Border Environmental Program

A Development of Guidelines and Health Criteria for the Cal EPA

Schools Risk Assessment Program

Oversight of contract research to develop transfer factors for
contaminants at school sites.

A Risk Assessment review and oversight for the State Water Resources
Control Board, the Integrated Waste Management Board, and local agencies
in California

- Previously served on the Governor's Panel of Experts in Carcinogen Identification
Professional activities and responsibilities do not involve external
grant or contract support

Calvin Chien

a. Current position

Senior Environmental Fellow

b. Educational background

B.S.E.(1966), Hydraulin Engg., National Taiwan Cheng Kung Univ,;

M.S.E.(1970), Hydrodynamics, State Univ. of N.Y. at Buffalo;
Ph.D. (1974), Hydrologic System Modeling, SUNY/AB.

c. Area of expertise and research activities

Subsurface Fate & Transport Modeling
Environmental Contamination Investigation and Remediation
Remediation Technology Evaluation

d. Service on other advisory committees, professional societies, especially those associated with issues under discussion in this review

USEPA Science Advisory Board: Environmental Engineering Committee and Environmental Modeling Subcommittee: Involved in the reviews of programs like TRIM, MMSoil, and other major models and modeling related programs between 1993-2001.

e. Sources of recent grant and/or contract support

None.

Edmund Crouch

Dr. Crouch is a Senior Scientist with Cambridge Environmental. He holds a B.A. in Natural Sciences (Theoretical Physics) (1972) and a Ph.D. in High Energy Physics (1975), both from Cambridge University, United Kingdom.

Dr. Crouch has published widely in the areas of environmental quality, risk assessment, and presentation and analysis of uncertainties. He has co-authored a major text in risk assessment, Risk/Benefit Analysis. Dr. Crouch serves as an expert advisor to various local and national agencies concerned with public health and the environment, and has served on National Academy of Science Committees. He has written computer programs for the sophisticated analysis of results from carcinogenesis bioassays; has developed algorithms (on the levels of both theory and computer implementation) for the objective quantification of waste site contamination; and has designed Monte Carlo simulations for purposes of fully characterizing uncertainties and variabilities inherent in health risk assessment.

Dr. Crouch is widely regarded as an insightful peer-reviewer; he has detected and corrected numerous, critical, otherwise hidden flaws in the technical underpinnings of proposed regulations for environmental protection and related areas. Specific committee and review experience includes:

- Committee on Risk-Based Criteria for Non-RCRA Hazardous Waste, National Research Council (Risk-Based Waste Classification in California)
- Committee on Health Effects of Waste Incineration, Board on Environmental Studies and Toxicology, National Research Council (Waste Incineration and Public Health)
- Committee to Review the CDC-NCI Feasibility Study of the Health Consequences from Nuclear Weapons Tests, National Research Council
- Provided comments (that were published as an appendix to the report) to: Committee on the Review of the USDA E. coli O157:H7 Farm-to-Table Process Risk Assessment, National Research Council

Dr. Crouch's work for Cambridge Environmental Inc. is supported by contracts and work on a time and materials basis with various private companies and law firms for risk assessment and related work.

Peter deFur

Dr. Peter L. deFur is president of Environmental Stewardship Concepts, an independent private consultant, serving as a technical advisor to citizen organizations and government agencies. He is an Affiliate Associate Professor in the Center for Environmental Studies at Virginia Commonwealth University where he conducts research on environmental health and ecological risk assessment. Dr. deFur is President of the Association for Science in the Public Interest (ASIP) and on the board of the Science and Environmental Health Network (SEHN).

Dr. deFur was previously a senior scientist at the Environmental Defense Fund (now ED) in Washington, DC and held faculty positions at two universities before that. He has extensive experience in risk assessment and ecological risk assessment regulations, guidance and policy. He served on the NAS/NRC various study committees, including the Risk Characterization Committee that released its report, Understanding Risk in June 1996. Dr. deFur served on numerous scientific reviews of EPA ecological and human health risk assessments, including the assessment for the WTI incinerator in Ohio and EPA's Ecological Risk Assessment Guidelines. deFur served on EPA's Endocrine Disruptor Screening and Testing Advisory Committee and is now on EDMVS.

Dr. deFur received B.S. and M.A. degrees in Biology from the College of William and Mary, in Virginia and a Ph.D. in Biology from the University of Calgary, Alberta. He was a postdoctoral fellow in neurophysiology in the Department of Medicine at the University of Calgary.

Dr. deFur conducts research on the identification of and effects of endocrine disrupting chemicals, particularly in aquatic crustaceans. He is also interested in the effects of low oxygen conditions on aquatic animals and systems in estuaries and coastal environments. deFur also conducts research on precautionary approaches to environmental regulations and on citizen involvement in environmental programs, policies and regulations

Dr. deFur was appointed to BEST of the National Academy of Sciences/National Research Council in

1996. He is on the Advisory Committee to the Board of the Coalition to Restore Coastal Louisiana, and a peer reviewer for professional journals. He has published numerous peer reviewed articles, invited perspectives and review articles for the public on subjects ranging from habitat quality to wetlands, toxic chemical and risk assessment.

During the past ten years, Dr. deFur has been extensively involved in scientific research, regulation and policy concerning the generation, release and discharge of dioxin and related compounds. He has published a number of papers on regulation and policy aspects of these compounds, considered in many ways prototype endocrine disruptors. Dr. deFur has been extensively involved in the EPA reassessment of dioxin since 1991. He was a technical advisor to the EPA Superfund Ombudsman office, and is presently technical advisor for the Port Angeles clean up of the Rayonier mill site, the water quality program in the state of Indiana, and to citizens groups for the Rocky Mountain Arsenal superfund site.

Dr. deFur serves as a technical consultant to citizen organizations that are involved in cleanup actions at contaminated sites around the country

Joseph DePinto is currently a Senior Scientist at Limno-Tech, Inc. an environmental consulting company specializing in the development and application of water quality and ecosystem models for addressing a myriad of problems in aquatic ecosystems.

He joined LTI in June, 2000 after spending 27 years in academia, including 10 years as Director of the Great Lakes Program at the University at Buffalo. During that time, Dr. DePinto was an active part of the Great Lakes research community and he is continuing in that role at Limno-Tech, Inc. During his professional career, Dr. DePinto has directed projects on such topics as nutrient-eutrophication, toxic chemical exposure analysis, contaminated sediment analysis and remediation, aquatic ecosystem trophic structure and functioning, and watershed, river, and lake modeling.

Recent projects, both prior to and subsequent to joining LTI, that are relevant to the subject SAB panel include (funding source in parentheses): development and application of an integrated exposure model for PCBs in Green Bay, Lake Michigan (EPA-ORD); development and application of sediment and contaminant fate and transport models to assess and evaluate remediation of contaminated sediments in several river systems, including the Buffalo River (EPA-Great Lakes National Program Office (GLNPO)), St. Clair River (Ontario Ministry of Environment), Lower Fox River (Fox River Group), Kalamazoo River (Kalamazoo River Study Group), Niagara River, and Hudson River (EPA-Reg 2 through TAMS); assisted the Delaware River Basin Commission in development of a PCB fate and transport model for application to a TMDL analysis for the Delaware River/Estuary (DRBC); led a team of scientists and engineers at the University at Buffalo in the development of a Geographically-based Watershed Analysis and Modeling System (GEO-WAMS), a Modeling Support System that coupled a Geographic Information System (ARC-INFO) with existing and newly developed watershed and water quality models (EPA-ORD); development and application of a contaminant fate, transport and bioaccumulation model for Lake Ontario in support of the development of a lakewide management plan (LaMP) and TMDL for that system (EPA-Region 2); and development of an aquatic ecosystem model for Saginaw Bay, Lake Huron to investigate the ecological impacts of zebra mussels on nutrient cycling and primary production and on PCB cycling and bioaccumulation (EPA, ORD and GLNPO).

Three relevant ongoing projects being conducted by LTI with Dr. DePinto as the Principal Investigator are: "Developing a Model Framework for Assessing Ecological Impacts of Water Withdrawals in the Great Lakes Basin" (Great Lakes Protection Fund); "Development of an integrated ecological response model for the International Joint Commission Lake Ontario – St. Lawrence River water levels/flows study" (USACE-IWR); and "Linking a fine scale hydrodynamic model (POM) for Lake Ontario with a course grid toxic chemical exposure model (LOTOX2)" (EPA-GLNPO through University at Buffalo).

Dr. DePinto has also participated in several workshops and advisory panels relevant to the topic. He participated in the SETAC Pellston Conference on "Criteria for Persistence and Long-Range Transport of Chemicals in the Environment," in 1998; was a Peer Reviewer for EPA, ERL-Duluth, on the Dioxin Aquatic Risk Assessment Report, (July 1993 - October, 1993); invited expert review panel member, "Workshop on Application of 2,3,7,8-TCDD Toxicity Equivalence Factors to Fish and Wildlife," EPA-sponsored workshop, Chicago, IL (January 20-22, 1998); invited member of Model Evaluation Group (MEG) for the Contamination Assessment and Reduction Project (CARP) of the New York/New Jersey Harbor Estuary Program (Oct. 2000 – present); commissioned reviewer, "Florida Pilot Mercury Total Maximum Daily Load (TMDL) Study" report prepared by Tetra Tech, Inc. for Florida Dept. of Environmental Protection documenting modeling work with E-MCM (April, 2000); is a member of the International Joint Commission, Council of Great Lakes Research Managers; and is an Associate Editor of the Journal of Great Lakes Research and Chair of the Publications Committee of IAGLR.

Dr. DePinto received his PhD in Environmental Engineering in 1975 from the University of Notre Dame, Notre Dame, Indiana. His studies have led to over 100 publications and the direction of more than 45 Master's theses and 12 Ph.D. dissertations

Alan Eschenroeder

Dr. Eschenroeder serves on the faculty of Harvard School of Public Health and operates an independent consulting firm. He received both his BME and PhD degrees in engineering at Cornell University. He has performed numerous risk assessments and has developed novel multimedia modeling techniques both for health and climate change investigations. His current area of research focuses on exposure analyses for

contaminants emitted during military actions in the Middle East conflicts. In addition to serving EPA as a peer reviewer over recent decades, he has served and chaired various National Academy of Science special committees and subcommittees (see CV for details). His most recent grant support has come from the US Agency for International Development, the China Project at Harvard, and the United Nations fund for reparations. Current support for consulting work derives from the law firm of Broiles and Timms, LLP on behalf of a private industrial client involved in litigation.

During the decade following his education and military service, he implemented computer-based tools in the field of hypersonic fluid dynamics to provide design inputs for space and defense applications. Using some of these same techniques he began the development of simulation models tracing the evolution of photochemical smog. This modeling work subsequently evolved into multimedia descriptions of contaminant fate and transport in air, water, soil and biota, as applied to exposure and health risk assessment. Examples of his recent research interests include: greenhouse gas tradeoffs in waste management, comparative health risks of rural burning versus controlled combustion of domestic waste in Slovakia, health impacts of mobile sources in China and the addition of socioeconomic influences to health risk assessments and life cycle analyses.

Jeffrey Foran

Dr. Foran is a broadly trained environmental scientist with expertise in toxicology, human and ecological risk assessment, and science-policy. He holds a Ph.D. in Environmental Sciences from the University of Florida, an M.S. in Biology from Central Michigan University, and a B.S. in Biology from the University of Michigan. Dr. Foran has served as a Scientist with the National Wildlife Federation, as Associate Professor at the George Washington University School of Medicine and Health Sciences, as Executive Director of the ILSI Risk Science Institute in Washington, D.C., and as Director of the UW-Milwaukee WATER Institute. Currently, he is President of Citizens for a Better Environment (CBE), is a private consultant for foundations and non-profit NGOs, and provides litigation support. He also holds an adjunct faculty position at the University of Michigan School of Natural Resources and Environment.

Dr. Foran is a member of both Tau Beta Pi (Engineering Honorary) and Sigma Xi (Scientific Research Honorary), he is a member of the Board of Directors of the Einstein Institute for Science, Health, and the Courts, and is President of the World Council of the Society of Environmental Toxicology and Chemistry (SETAC). He has served as an advisor and consultant to numerous organizations including the U.S./Canadian International Joint Commission, the Organization for Economic Cooperation and Development (OECD), the World Health Organization, the International Program on Chemical Safety (IPCS), the U.S. Environmental Protection Agency, Centers for Disease Control and Prevention, the U.S. General Accounting Office, and the U.S. Dept. of Defense.

Robert Giraud

a. Current position

Senior Consultant, Environmental Engineering, DuPont Engineering Technology

b. Educational background

B.S. Chemical Engineering, Tulane University, 1980; Master's, Chemical Engineering, Tulane University, 1983

c. Area of expertise and research activities

Hazardous Waste Regulatory Compliance, Industrial Nonhazardous Waste Management, Hazardous Waste Combustion Technology, Multimedia Human Health Risk Assessment, Pollution Prevention

d. Service on other advisory committees, professional societies, especially those associated with issues under discussion in this review

FACA – Industrial Nonhazardous Waste Focus Group 1997 – 2003; Ad hoc chemical industry technical review team – review and comment on EPA “Screening Level Ecological Risk Assessment Protocol”, 2000; Waste Minimization and Combustion Coalition technical team – review and comment on EPA “Guidance for Performing Screening Level Risk Analyses at Combustion Facilities Burning Hazardous Wastes, 1994

e. Sources of recent grant and/or contract support

DuPont employee 1980 – present

Barbara Harper

Current position: Partner and senior scientist with AESE, Inc. We are a small consulting firm providing technical support only to Tribes (we have no non-tribal clients) in toxicology, subsistence exposure scenarios, multipathway/multimedia/multicontaminant risk assessments, contamination of subsistence resources, Superfund cleanup and regulatory oversight, geology, public health, cultural risk, tribal regulatory standards, and related matters. Dr. Harper also has an adjunct research associate professor at Oregon State University.

Education: Dr. Harper is a board-certified toxicologist. She received her PhD in zoology (genetics) from the University of Texas at Austin in 1974.

Area of expertise and research activities: Dr. Harper is a toxicologist and risk assessor with special expertise in developing exposure factors for tribal risk assessments that reflect traditional lifeways and use of subsistence resources.

Advisory Committees, professional societies: Dr. Harper has been involved in many of the tribal advisory committees used by EPA, and has provided training on risk assessment to many tribal groups dealing with EPA models. She is also on the SAB Drinking Water Committee. She belongs to the Society for Risk Analysis, SETAC, Am. Anthropology Society (Council for Nutritional Anthropology), the Society for Ethnobiology, and other groups not related to the topic under review.

Recent grant and contract support: All of our company support is via contracts with Indian Tribes. In addition, Dr. Harper recently received an EPA-STAR grant through Oregon State University for research on tribal exposure scenarios and exposure factors. These factors are based on traditional lifeways and native diets, and are used as inputs into risk assessment models such as the one under review. Because tribal lifeways are different from the suburban lifestyles that the EPA default exposure factors were developed for, we focus on ensuring that tribal-appropriate exposure factors are used in risk assessments related to contamination of tribal resources and exposure of tribal members

Bruce Hope

Bruce Hope is with the Oregon Department of Environmental Quality (DEQ), where he serves as a senior environmental toxicologist for the Land Quality Division. He is presently involved with preparation of sediment evaluation guidance for use by DEQ project managers and with developing an aquatic food web biomagnification model for mercury target analysis as part of the Willamette River TMDL process. He is also responsible for reviewing and commenting on human health and ecological risk assessments prepared by contractors for specific cleanup sites, confirming remedial action levels, and evaluating remedial alternatives for various media (soil, water, air, sediment, groundwater). Other assignments have included drafting risk assessment rule language required by Oregon's revised cleanup law, developing guidance (human health, ecological, probabilistic) needed for effective implementation of these new rules, and leading the State's efforts to implement probabilistic human health assessments and population-level ecological assessments. In 2000-01, he was on leave from DEQ as an American Association for the Advancement of Science (AAAS) risk policy fellow at the U.S. Department of Agriculture in Washington DC, where he worked on food safety and microbial risk issues.

Prior to joining DEQ in 1995, he was a consultant in the private sector managing preparation of human health and ecological risk assessments for commercial and government clients at CERCLA, RCRA, and BRAC sites throughout the U.S. and Pacific Rim. He has also served on several U.S. EPA advisory panels including: a Scientific Advisory Panel addressing probabilistic analyses under the Federal Insecticide, Fungicide, and Rodenticide Act, the Science Review Board for the Food Quality Protection Act, a peer review workshop on the Process for Conducting Probabilistic Risk Assessment for Superfund and a Risk Assessment Forum workshop on probabilistic assessments. He has written peer-reviewed and technical publications on toxicology, risk assessment, and geochemistry, and has a special interest in exposure modeling. Dr. Hope is an adjunct faculty member at Oregon Health & Science University (Oregon Graduate Institute, School of Nursing), Concordia University, and Portland State University. He holds M.S. and Ph.D. degrees in biology (aquatic toxicology) from the University of Southern California and a B.A. degree from the University of California (Santa Barbara). He is presently supported exclusively by employment with the State of Oregon. There is no current grant support and recent contract activity has been limited (<\$2000/yr) to the U.S. Army ARAMS program

Michael Lakin

Dr. Michael L. Lakin
Principal, EnSIGHT, LLC
B.S. Biochemistry, UC Davis
Ph.D. Environmental Toxicology and Pharmacology, UC Davis

Risk Assessment, Toxicology, Regulatory Toxicology, Multimedia Modeling to support Risk-Based Decisions

Cal EPA, Regulatory Structure Update, Waste Classification and Disposal Requirements Advisory Group

No Grants or General Support Contracts

All work conducted by EnSIGHT is conducted under contract. All contracts are with private parties, typically from Fortune 1000 companies. The only work performed which was related to waste classification is my participation in the evaluation of the California proposed risk-based waste classification rule. In that instance EnSIGHT was retained by the California Business Council, who in turn was reimbursed by several industry consortia of companies which included the petroleum industry, chemical industry and the energy-utility industry.

Guy R. Lanza is a Professor of Microbiology and Director of the Environmental Sciences Program at the University of Massachusetts at Amherst, and Director of the Graduate Program in Environmental Toxicology and Risk Assessment. Dr. Guy R. Lanza has been involved in

research, teaching, curriculum development, and consulting in several areas of the environmental sciences including ecotoxicology, environmental impact assessment, applied and environmental microbiology, aquatic ecology, and water quality for more than 30 years.

He has completed studies to develop and implement novel methods for measuring and monitoring ecotoxicological effects in soil, water, and sediments, including sediment microbial enzyme activity tests for detecting toxicant impacts. He has also directed several research projects on bioremediation and phytoremediation strategies suitable for hazardous waste sites. Dr. Lanza has also done research on the ecology of infectious diseases and is currently involved in environmental impact assessments of several major hydroelectric dam projects in Asia and Africa. Dr. Lanza is Senior Science Editor of the International Journal of Phytoremediation (CRC Press - Taylor Francis) and is an Editor of the journal Ethics In Science and Environmental Politics.

He has a Ph.D. in Biology/Environmental Microbiology from Virginia Polytechnic Institute and State University and is a Fellow of the American Academy of Microbiology. Dr. Lanza's current/recent research has been funded by grants from the Massachusetts Department of Environmental Management, and from university research grants.

Leonard Levin

Position: Technical Leader, EPRI; Program Manager, EPRI Program in Air Toxics Health and Risk Assessment; Issue Leader, Environmental Mercury

Education: Ph.D. (Univ. of Maryland); M.S. (Univ. of Washington); B.S. (MIT)

Expertise: Environmental modeling; environmental fluid dynamics (air and water flow and cycling); human exposure and risk analysis; trace substance dynamics

Service: Peer reviewer: EPA Mercury Study Report to Congress; EPA Mercury Research Strategy; US DOE Waste Management Strategy; U. California at Berkeley Advisory Panel on Environmental Management curriculum; Air & Waste Management Association. Section President, Society for Risk Analysis. Invited lecturer, Society for Environmental Toxicology and Chemistry. Review panel on mercury monitoring, SETAC. Review panel on air toxics monitoring, U.S. EPA. Many others.

Support: primarily EPRI base funding. Awardee, U.S. DOE NETL contract, October 2002. Awardee, State of Wisconsin Focus on Energy program, 2002. Peer reviewer, American Chemistry Council. (2003)

Igor Linkov

Dr. Linkov is a Senior Risk Assessor and Team Leader with ICF Consulting, Inc. Dr. Linkov has a BS and MSc in Physics and Mathematics (Polytechnic Institute, Russia), a MS equivalent in Engineering and Public Policy (Carnegie-Mellon University), and a PhD in Environmental, Occupational and Radiation Health (University of Pittsburgh). He completed his postdoctoral training in Biostatistics and Toxicology at Harvard University.

He has more than 13 years of experience in performing cutting edge ecological and human health risk assessments and environmental investigations for contaminated sites in the U.S.A and internationally. Dr. Linkov's skills include project probabilistic modeling, human health and ecological risk assessment, guidance development, risk communication, litigation support, policy analysis, toxicology and biostatistics. He has also developed software for environmental modeling, decision support and risk assessment. His current research interests include developing risk-based approaches to environmental decision making. He has published widely on environmental policy, environmental modeling, and risk analysis, including four books and over 60 scientific papers. He has organized and directed five international conferences on ecological risk assessment, on comparative risk assessment, on the role of risk assessment in addressing bioterrorism, on contaminated forests, and on air pollution.

Dr. Linkov serves as a Scientific Advisor to the Toxic Use Reduction Institute, a position that requires nomination by the Governor of Massachusetts. Dr. Linkov is President-Elect for the Society for Risk Analysis-New England. He also chairs the Ecological Risk Assessment Specialty group for the Society for Risk Analysis and participates in several SRA and SETAC Committees. Dr. Linkov has served on various review and advisory panels for the US and international agencies. He is currently managing a probabilistic ecological risk assessment for a Superfund site for the US Army as well as several projects for EPA/ORIA and EPA/OST/HECD that involve advanced statistical analyses and modeling. Dr. Linkov is also developing models and software to incorporate habitat quality and spatial scales into ecological risk assessment for the US Army, American Chemistry Council and NOAA.

Randy Maddalena

Randy Maddalena, Ph.D., is a Scientist in the Exposure and Risk Analysis Group within the Environmental Energy Technologies Division at Lawrence Berkeley National Laboratory. He received his BS in Environmental Toxicology (1992) and his Ph.D. in Agricultural and Environmental Chemistry (1998) from the University of California, Davis.

The primary focus of his research is development, evaluation and application of models that predict chemical fate in multiple environmental media (air, water, soil, vegetation, sediment) and chemical exposures through multiple pathways (drinking water, food, feed, indoor air) for both human and ecological receptors.

He also develops tools and methods for performing probabilistic risk assessment and sensitivity analysis applied to complex regulatory models. His most recent work combines the use of models and experimental data to investigate how vegetation influences the environmental fate and transport of semivolatile organic pollutants and how the uptake of these pollutants into ecological or agricultural food chains might contribute to dietary exposures.

Dr. Maddalena is a Co-chair of the Society of Environmental Toxicology and Chemistry (SETAC) Advisory Group on Fate and Exposure Modeling where he serves as an Editor of the Fate and Exposure Modeling column in the SETAC Globe. He is also a member of the International Society of Exposure Analysis and a member of the SAB's Integrated Human Exposure Committee. He receives funding from the EPA's National Exposure Research Lab for research on fate and exposure models; the DOE's Fossil Energy Program for experimental work on plant uptake of petroleum related hydrocarbons; and from the EPA's Office of Air Quality Planning and Standards for his work on the TRIM.FaTE model. Dr. Maddalena also recently completed a project funded by the EPA's Office of Emergency and Remedial Response where he developed a standardized approach for constructing inputs to probabilistic risk assessment models.

Alan Maki

Alan W. Maki received his BSc. in Fisheries Biology from the University of Massachusetts, his MSc. in Environmental Toxicology from the University of North Texas, and holds a Ph.D. in Wildlife and Fisheries Management from Michigan State University. He is currently Senior Environmental Advisor for ExxonMobil Production Company and is responsible for providing advice and consultation concerning the environmental consequences of oil and gas exploration and production activities. He previously worked at ExxonMobil Biomedical Sciences in East Millstone, New Jersey and with the ExxonMobil Safety, Health and Environment Department in Houston, Texas. He served as Senior Environmental Scientist for Exxon in Alaska from 1985 to 1991 managing numerous environmental programs in the Prudhoe Bay oil field and along Alaska's North Slope. Following the Exxon Valdez oil spill, he was responsible for managing Exxon's wildlife rescue rehabilitation program and for organizing the company's scientific assessment of ecological damage and recovery.

Dr. Maki has authored and co-authored over 250 publications and reports and 6 books on numerous aspects of environmental quality, fate and effects of chemicals in the environment, ecological risk assessment, toxicology and aquatic biology.

Active in a wide range of professional organizations, Dr. Maki is a former member of the Environmental Protection Agency - Science Advisory Board and has served on numerous advisory panels for EPA Office of Research and Development. He is former President of the Society of Environmental Toxicology and Chemistry, and has served on National Academy of Science panels concerned with the assessment and management of ecological risks, and a panel to review environmental contamination issues in Western Europe.

Dr. Maki's work is fully supported by ExxonMobil.

David Merrill

Mr. Merrill, a Principal at Gradient Corporation, has 15 years of experience in negotiating technically sound and cost effective solutions to environmental contamination problems. His expertise includes directing large-scale, multi-disciplinary risk assessments, multimedia chemical fate and transport modeling, complex data analysis, and database design for systems such as landfills, lagoons, chemical plants, MGPs, river systems, and groundwater contaminant plumes. With his extensive risk assessment experience and strong engineering background, he has negotiated risk-based cleanup levels and remedial strategies, interpreted complex site investigation data into effective conceptual site models, and evaluated many types of contaminant transport conditions, including multimedia transport in water, sediments, and air. He has worked extensively with PCBs, solvents, metals and NAPLs and has served as an expert on cases involving PRP cost allocation disputes. Mr. Merrill has prepared technical comments on behalf of industry and trade organizations on Agency regulations including the PCB Megarule and multimedia modeling and risk assessment aspects of the LDR and the HWIR Rules.

All of Mr. Merrill's professional work is performed for Gradient. Gradient's client base includes Fortune 500 companies, law firms, trade associations, and to a lesser extent state and local municipalities and regulatory agencies. Over the last two years Mr. Merrill's clients have included law firms representing individual companies and PRP groups, trade associations, chemical companies, natural gas pipeline and oil companies, energy generation companies, and the U.S. EPA. Mr. Merrill received his B.S. in Soil and Water Science from the University of California at Davis, and his M.S. in Agricultural Engineering (Civil/Environmental Engineering focus) from Cornell University where he also completed the coursework and qualifying exams toward a doctorate degree.

Ishwar Murarka

a. Current position

Chief Scientist and President of Ish Inc. – a minority owned environmental consulting business. Visiting research associate at the University of Illinois in Chicago.

b Educational background

Ph.D. Soil Science and Statistics (1971), MBA. Management Science (1974)

c. Area of expertise and research activities

Environmental Science and Technology topics pertaining to:

- Management of solid and liquid wastes,
- Characterization and Assessment of contaminated sites
- In-situ Treatment Technologies (e.g. Chemical oxidation)
- Remediation/restoration of impacted land, groundwater, and sediments.

My research activities cover transport, transformation, and fate of metals and organic compounds in the land and water environments.

d. Service on other advisory committees, professional societies, especially those associated with issues under discussion in this review

I serve on the External Advisory Committee of the Institute for Environmental Science & Policy for University of Illinois in Chicago.

I serve as Peer Reviewer on Mercury Studies for EPA

I continue to be a consultant for the EPA Science Advisory Board.

Involved in US Experts Panel for an USAID project in India

e. Sources of recent grant and/or contract support

I have research granted/funding from USDOE/CBRC, EPRI, GTI, and NYGAS.

I also receive contract support on projects involving characterization and remediation of contaminated sites from various utility companies (e.g., Duke Energy, NYSEG, RG&E, Consumers Energy, Georgia Power, We Energy, First Energy, NISOURCE, SCANA, etc.

Paul Price

Mr. Price is a modeler and researcher on exposures to chemicals. He is a director of The LifeLine Group, a non-profit corporation developing software for the assessment of exposure to pesticides and other substances. Mr. Price has more than 20 years of experience in assessing exposure to chemicals for industry, government, and trade associations. He has authored over 20 articles on exposure and risk assessment. Areas of interest include Monte Carlo modeling, dose reconstruction, aggregate and cumulative risk, consumer products and pesticide exposures. Mr. Price has a Masters degree in Civil Engineering (University of Maryland, 1979) and a Bachelors degree in Chemistry (University of Maryland, 1974). Mr. Price has served on advisory boards for EPA, The State of California, and the Army Corp of Engineers.

The LifeLine Group is funded by contracts and grants from USEPA, the American Chemistry Council, Health Canada, and the Department of Defense. Current projects include the modeling of aggregate and cumulative exposures to pesticides, exposures to pesticides in tribal communities, and the development of models of uncertainty and variability in exposure to riot control agents in crowds.

Bradley Sample

Dr. Sample is an ecotoxicologist with over 10 years of experience as an ecological risk assessor and wildlife ecologist focusing on large, complex sites. As a Principal Technologist, he leads risk assessment projects for both state and federal government and industry and serves as CH2M HILL's Southwest Regional ecological risk assessment leader.

Dr. Sample has assisted clients with Federal and State agency liaison and guidance documents, risk management, ecological risk assessment strategy, and risk management planning. He specializes in wildlife toxicology of organic and inorganic contaminants, contaminant bioaccumulation, foodweb and ecological modeling, probabilistic risk assessment, data analyses, and biota sampling, applied statistics, and experimental design. He has extensive experience in evaluation of ecological risks from metals, chlorinated organics, and petroleum compounds. His background covers entomology, ornithology, and mammalogy, in addition to statistics and experimental design.

He serves on the steering committee and developed the wildlife exposure model for the EPA's Ecological Soil Screening Levels (EcoSSLs). He is currently developing the wildlife modeling component and over-seeing software development for the Army Risk Assessment Modeling System (ARAMS). He has conducted risk assessments in support of CERCLA and RCRA, and worked on projects for the numerous federal clients (US Army, Navy, Air Force, Coast Guard, US EPA, and US DOE) and private clients (Unocal and Chevron). Dr. Sample is a co-author of a book on ecological risk assessment at contaminated sites, and currently serves on the editorial board of the journal Environmental Toxicology and Chemistry. Elected to the Board of Directors of the Northern California Chapter of the Society for Environmental Toxicology and Chemistry in 2001, he currently serves as the chapter Vice-President. Due to Dr. Sample's expertise, he has twice been invited to serve on peer-review committees for the ecological risk assessment and bioaccumulation modeling components of the U.S. EPA's Hazardous Waste Rule.

Mitchell Small

Mitchell Small is the H. John Heinz III Professor of Environmental Engineering in the Departments of Civil

& Environmental Engineering and Engineering & Public Policy at Carnegie Mellon University. He joined Carnegie Mellon in 1982 following completion of his Ph.D. in Environmental & Water Resources Engineering from the University of Michigan. At Carnegie Mellon, Professor Small serves as the Associate Department Head for Graduate Education in the Department of Engineering & Public Policy. He has also worked as a consulting engineer, with Hydrosience, Inc., from 1975-1978.

Mitchell Small's research involves mathematical modeling and statistical evaluation of environmental quality, exposure and risk. He has developed methods for statistical modeling of variability and uncertainty for air, soil, surface-water and ground-water problems. His recent work has evolved to consider the impact of human risk perception and behavior in integrated exposure assessment, and has included collaboration with statisticians, toxicologists, economists, and behavioral and decision scientists. Current applications include the study of regulations and risk communication for drinking water utilities, contaminated site and soil remediation, and decision support for environmentally sustainable products and infrastructure. Support for this research has come from a number of government agencies and private industry, including a National Science Foundation Presidential Young Investigator Award from 1986-1991.

Professor Small has been active in providing advice to the US Environmental Protection Agency as a member of the Science Advisory Board (SAB) Environmental Engineering Committee (1985-1991) and currently as Chair of the SAB Environmental Modeling Committee. He was a charter member of the EPA ORD Board of Scientific Counselors (BOSC) from 1996-2002, and participated on a number of National Research Council (NRC) study panels, most recently the NRC Committee on Risk Characterization and the Committee on Environmental Remediation at Naval Facilities, helping to formulate the Committee's vision for its recently released report on "adaptive site management." He currently serves as an associate editor for the journal Environmental Science & Technology, with particular responsibility for the Policy Analysis section. He recently completed an assignment as an elected Councilor of the Society for Risk Analysis (SRA), and remains active with the SRA as a member of the planning committee and white paper collection editor for its upcoming World Congress on Risk. A full CV for Dr. Small is available at http://www.epp.cmu.edu/people/EPP_faculty.html.

Current research projects are supported by the US EPA Office of Research and Development, the National Science Foundation, the David and Lucile Packard Foundation, and the Vira I. Heinz Endowment through the funding of the H. John Heinz III Professorship of Environmental Engineering at Carnegie Mellon University.

Doug Smith

Douglas G. Smith, Sc.D. is a Principal Scientist in ENSR's Risk Assessment group with degrees in Environmental Health Sciences (specializing in Air Pollution and Industrial Hygiene) and Physics. He has 28 years of experience in risk assessment of toxic airborne materials, including atmospheric transport and diffusion modeling, with applications to environmental siting and permitting.

Most recently, Dr. Smith has also led more than a dozen multi-pathway risk assessment projects in support of RCRA permitting and strategic planning for chemical industry members who use incinerators, or boilers and industrial furnaces (BIFs) for waste disposal and energy recovery. These projects are active in U.S. EPA Regions 2, 3, 4, 5, and 6 and have included supporting applications or updates for permits in New York, New Jersey, Ohio, Pennsylvania, Illinois, Georgia, Kentucky, Tennessee, W. Virginia, Louisiana, and Texas. In early 2000, Dr. Smith presented ENSR's team findings in response to an EPA request for an independent external peer review of their "Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities." Dr. Smith has also provided expert testimony on several other occasions for chemical industry clients in toxic tort proceedings and has authored more than 25 publications and technical presentations on hazardous air pollutants, modeling issues and accidental releases. His Sc.D. and M.S. degrees in Environmental Health Sciences are from Harvard University School of Public Health, and his A.B. in Physics is from Franklin and Marshall College.

In addition, Dr. Smith has provided expert advice and support to clients in the chemical and pharmaceutical industries on exposure and risk analysis, as well as emergency response planning, preparedness and communication requirements for effective risk management programs. This support has included overall program design, as well as training and auditing for OSHA's Process Safety Management (PSM) rule, and U.S. EPA's Risk Management Planning (RMP) rule.

Harlee Strauss is the President of H. Strauss Associates, Inc. (HSAI), a consulting firm she founded in 1988. Dr. Strauss works on a broad range of projects, from site specific human health risk assessments, to in-depth evaluations of the toxicity of individual chemicals, to the development of frameworks for risk assessment. Current contract support (ultimately from EPA) includes technical team leadership for the human health risk assessment of the GE/Housatonic River Site/Rest of River. Other recent consulting work, for both private and public sector clients, includes conducting site specific human health risk assessments and providing expert witness and litigation support services. In 1994-95, Dr. Strauss initiated and, for its first year lead, a multimillion dollar study to investigate the potential links between the environment and breast cancer on Cape Cod, Massachusetts.

Dr. Strauss earned a Ph.D. in molecular biology from the University of Wisconsin - Madison in 1979 and an A.B. in chemistry from Smith College in 1972. She was a postdoctoral fellow in biology at MIT (1979-81, sponsored by the NIEHS) and a Congressional Science Fellow sponsored by the Biophysical Society (1981-

83).

Dr. Strauss has served on several EPA Peer Review Committees, including the Evaluation of PCBs in the Hudson River, Drake Chemical Site Incinerator, and Proposed Bioaccumulation Testing Evaluation Framework for Determining the Suitability of Dredged Material to be Placed at the Historic Area Remediation Site (HARS) in Region 2.. She was an invited participant in EPA's "Exposure Factors Handbook Workshop" in July, 1993.

Dr. Strauss served as a member of the U.S. Army Science Board from 1994-2001, and participated in studies regarding lead-based paint, groundwater and soil remediation at Army facilities, Chem/Bio Weapons Defense, and the Range Rule (pertaining to unexploded ordinance). She also participated in the toxicology and risk characterization subcommittees for the Office of Research and Standards, MA Department of Environmental Protection revision of risk assessment guidance under the Massachusetts Contingency Plan in the early 1990's and numerous workshops on biotechnology risk assessment and regulatory policy, including the EPA Workshop on Large Scale Field Trials (1991), EPA Biotechnology Monitoring Workshop (1988), and Keystone Biotechnology Forum (1986-1988). Dr. Strauss served on the advisory committee for the Society for Risk Analysis Workshop "Key Issues in Carcinogen Risk Assessment Guidelines." She is a community member of the Restoration Advisory Board of the U.S. Army's Soldiers Systems Center (Natick Labs) and an elected Town Meeting member in Natick Massachusetts.

William Stubblefield

Dr. William Stubblefield is a senior environmental toxicologist with Parametrix, Inc. in Corvallis, Oregon; he also holds a courtesy faculty appointment in the Department Molecular and Environmental Toxicology at Oregon State University.

Dr. Stubblefield has more than 15 years of experience in environmental toxicology, ecological risk assessment, water quality criteria derivation, and aquatic and wildlife toxicology studies. He has authored more than 50 peer-reviewed publications and technical presentations in the areas of aquatic and wildlife toxicology and environmental risk assessment. He is a co-editor of a recently published book entitled, "Re-evaluation of the State of the Science for Water Quality Criteria," that specifically examines the issues and approaches to be used in the evaluation of environmental impacts associated with contaminants in multiple media. Dr. Stubblefield's research efforts have looked at the fate and effects of metal and hydrocarbon contaminants in the environment and the relationships between these contaminants in the water/sediment/soil compartments.

He has also investigated food chain concerns through research efforts such as the investigation of metals transfer in resident aquatic and terrestrial organisms on Alaska's North Slope. His most recent research uses a combination of laboratory and field methods to investigate the effects of storm water-associated short-term pulse exposures of metals to aquatic organisms and examines the fate and disposition of storm water-associated metals in natural systems.

About 70% of Parametrix projects are funded by municipal and other government agencies the remainder are industrial clients. Funding for the majority of Dr. Stubblefield's metal related work comes from industrial trade associations or not-for-profit research organizations working in cooperation with U.S. EPA. Dr. Stubblefield is an active member of the Society of Environmental Toxicology and Chemistry, where he serves as the Society's vice-president, member of the Board of Directors, chairman of the Publications Advisory Council, chairman of the SETAC's Metals Advisory Group, past member of the Editorial Board for Environmental Toxicology and Chemistry, and 2002 annual meeting co-chair. He has been an invited participant at a number of scientific and regulatory conferences, served on U.S. EPA peer-review panels, and frequently acts as a technical reviewer for a number of scientific publications.

Dr. Stubblefield has a Ph.D. in Environmental Toxicology from the University of Wyoming, a M.S. degree in Toxicology/Toxicodynamics from the University of Kentucky, and a B.S. in Biology from Eastern Kentucky University.

Neil Sturchio

a. Current Position:

Professor of Geochemistry and Head, Department of Earth and Environmental Sciences,
University of Illinois at Chicago (UIC); Director, UIC Environmental Isotope Geochemistry Lab.

b. Education Background:

Ph.D., Earth and Planetary Sciences, Washington University, 1983
B.S. (honors), Earth Sciences, Fairleigh Dickinson University

c. Areas of Expertise and Research Activities

Geochemistry of natural waters, environmental isotope geochemistry, mineral-water interface geochemistry, application of stable isotope measurements to assessment of biodegradation of chlorinated solvents and perchlorate, environmental forensics, application of synchrotron radiation to studies of mineral-water interfaces and trace element speciation

d. Service on Relevant Committees

Proposal Review Panel for DOE Environmental Management Science Program, May 2002
On the editorial boards of the journals Chemical Geology and Environmental Forensics.

e. Sources of recent grant and/or contract support

U. S. Department of Energy
U. S. National Science Foundation
U. S. Department of Agriculture
National Aeronautics and Space Administration (May 2003)

Daniel Tessier is an Assistant Professor in the Division of Environmental & Occupational Health Sciences, School of Public Health, University of Illinois, Chicago. He has held this position since 2000, and his specific responsibilities are research and teaching in the areas of environmental and occupational toxicology.

Dr. Tessier's educational background includes a B.S. in analytical chemistry and an M.S. and Ph.D. in Pesticide Toxicology, all from the University of Massachusetts - Amherst. His thesis and dissertation research was under Dr. J. Marshall Clark, on the genotoxicity and immunochemical analysis of environmental breakdown products of an herbicide, alachlor, which is a common ground and surface water contaminant. Dr. Tessier received postdoctoral training under Dr. Fumio Matsumura at the University of California -Davis. His research there on the molecular and cellular toxicology of endocrine disrupting pollutants was supported by a National Institutes of Health Training Fellowship.

Dr. Tessier has expertise in the areas of molecular and cellular toxicology as it relates to adverse effects of chemical exposures to humans, and the movement and fate of pesticides and other chemicals in the environment. His current research activities are focused on the molecular and cellular toxicology of endocrine disrupting pesticides and of metals. The endocrine disrupter research is aimed at understanding mechanisms of hormonal carcinogenesis that may be influenced by some environmental pollutants. The metals research is focused on these hazards as factors in the development of occupational asthma among welders. Dr. Tessier has research funding from the National Office of the American Lung Association, the University of Illinois Office of the Vice Chancellor for Research and the Illinois Education and Research Center. Dr. Tessier has served on the Grant Review Panel of the EPA STAR Program (Extramural Grants: Novel Mechanistic Approaches in Human Health Risk Assessment 2001), but has not served on other advisory committees to date.

Thomas Theis

Professor Thomas L. Theis is Professor of Civil and Materials Engineering and Director of the Institute for Environmental Science and Policy at University of Illinois at Chicago, a center that focuses on the development of new cross-disciplinary research initiatives in the environmental area. He was most recently at Clarkson University, where he was the Bayard D. Clarkson Professor and Director of the Center for Environmental Management.

Professor Theis received his doctoral degree in environmental engineering, with a specialization in environmental chemistry, from the University of Notre Dame. His areas of expertise include the mathematical modeling and systems analysis of environmental processes, the environmental chemistry of trace organic and inorganic substances, interfacial reactions, subsurface contaminant transport, hazardous waste management, industrial pollution prevention, and industrial ecology. He has been principal or co-principal investigator on over forty funded research projects totaling in excess of eight million dollars, and has authored or co-authored over one hundred papers in peer reviewed research journals, books, and reports.

He is a member of the USEPA Science Advisory Board (Environmental Engineering Committee), is past editor of the Journal of Environmental Engineering, and serves on the editorial boards of The Journal of Contaminant Transport, and Issues in Environmental Science and Technology. From 1980-1985 he was the co-director of the Industrial Waste Elimination Research Center (a collaboration of Illinois Institute of Technology and University of Notre Dame), one of the first Centers of Excellence established by the USEPA. In 1989 he was an invited participant on the United Nations' Scientific Committee on Problems in the Environment (SCOPE) Workshop on Groundwater Contamination, and in 1998 he was invited to by the World Bank to assist in the development of the first environmental engineering program in Argentina. Among his current projects is the Environmental Manufacturing Management Program, one of the Integrative Graduate Education Research and Training (IGERT) grants of the National Science Foundation, which involves research on industrial pollution prevention problems emphasizing a systems approach.

Louis Thibodeaux

Louis Joseph Thibodeaux is currently the Jesse Coates Professor in the Gordon A. and Mary Cain Department of Chemical Engineering, College of Engineering, Louisiana State University, Baton Rouge, LA.

His terminal degree is a Ph.D. in chemical engineering and presently his teaching, research and service is dominated by the field of environmental chemodynamics. Another name is chemical fate and transport in multimedia compartments of the natural environment. Current areas of research expertise include chemical release processes to water from sediment beds and to air from soil-like dredged materials as well as chemical releases to water and air from environmental dredging activities. The key area of educational expertise is the textbook entitled: ENVIRONMENTAL CHEMODYNAMICS in its 2nd Edition, published by J. Wiley(NY) in 1996. It is used by practitioners worldwide and by numerous universities in engineering, environmental chemistry, geosciences and other

environment oriented academic departments. Although he is the Emeritus Director of the USEPA funded South and Southwest Hazardous Substance Research Center, head quartered at LSU and Directed by Danny D. Reible.

Professor Thibodeaux has served on advisory committees for the USEPA, USACE, DOD, DOE, NRC and the private sector; all being related to environmental chemodynamic issues. He is a member of the Env. Div. of the Amer. Chem. Soc., Society of Env. Tox. and Chemistry and the Env. Div. of the Amer. Inst. Chemical Eng.

Professor Thibodeaux is fully employed by LSU doing research and teaching both graduate and undergraduate students. He also serves on the editorial board of several environmental journals and is presently receiving grant and/or contract support on four research projects from the USEPA and the USACE. Through the cooperative agreement USEPA/LSU in the S/SW Haz Res. Ctr., ORD Wash, DC. he receives research project funds. He also receives research funds from the US Army Corp. Engineers; the group is ERDC or Waterway Experiment Station, Vicksburg, MS.

Curtis Travis

Dr Curtis Travis has more than 25 years experience in the energy and environmental business sector and has published widely in the areas of environmental policy, molecular biology, and risk analysis. He holds a B.S. and M.S. in Mathematics from California State University (Fresno) and earned a Ph.D. in Applied Mathematics from the University of California (Davis). He is an internationally recognized expert in the field of risk analysis, and was the founding Director of the Center for Risk Management at Oak Ridge National Laboratory, where he was employed for 18 years.

He has worked in many areas of risk analysis including multimedia modeling, food chain uptake, pharmacokinetics, interspecies extrapolation, dose-response, and risk policy. Recently, he has worked on the cleanup of DOE hazardous waste sites, risk assessment for antimicrobial drug use in animals, and security issues related to food infrastructure in the United States.

Dr. Travis has authored over 270 publications, 8 books, and is on the editorial board of seven international journals. He has served on numerous National Academy of Science panels and governmental and private advisory boards. He is a past President and Fellow of the International Society of Risk Analysis and served as Editor-in-Chief of Risk Analysis: An International Journal for 17 years.

Dr. Travis is a private consultant with his own firm, Quest Technologies. Almost all his work is for government agencies: the Department of Energy, the Food and Drug Administration, and the Department of Agriculture. He has received no financial support from EPA in the past 10 years, other than in a review capacity.

Noel Urban

N.R. Urban is currently associate professor in Environmental Engineering at Michigan Technological University where he has been on the faculty since 1995. He received a B.A. in Russian Language and Culture and a B.S. in Environmental Engineering from Syracuse University in 1979. His M.S. and Ph.D. degrees were obtained at the University of Minnesota in the Dept. of Civil and Mineral Engineering. N.R. Urban is a biogeochemist focusing on major element cycles, nutrients, trace metals and radionuclides in lake and wetland environments. Recent research support has come from NSF, NOAA, New York City Dept. Environmental Protection, Headstart Child-Development Center, and the Michigan Great Lakes Protection Fund.

Gary Walter

Dr. Gary Walter is a Principal Scientist with the Center for Nuclear Waste Regulatory Analysis (CNWRA) at the Southwest Research Institute (SWRI). The CNWRA is a FFRDC funded by the Nuclear Regulatory Commission. The primary mission of the CNWRA is to provide the Nuclear Regulatory Commission with support for resolving technical issues related to the national geologic repository for high-level nuclear waste. The CNWRA investigates fundamental physical, chemical and geologic processes related to quantitative risk assessment for the repository. Dr. Walter's performs analyses of hydrogeologic issues related to the fate and transport of radioactive isotopes including numerical modeling of groundwater flow and transport. The CNWRA also supplies its expertise in hydrology, geology, and geochemistry to industrial and governmental clients in areas not related to the national high-level nuclear waste repository.

From 1983 to 2002, Dr. Walter was a Principal with Hydro Geo Chem, Inc., a private consulting firm providing services in the areas of environmental site investigation, fate and transport analysis, and environmental remediation. At Hydro Geo Chem, Dr. Walter managed various projects related to soil and groundwater contamination by volatile and semi-volatile organic compounds (including chlorinated and petroleum hydrocarbons) and metals. This work included developing numerical models for simulating the reactive transport of metals, simulating groundwater transport of biodegradable organic compounds, and vapor-phase transport of organic compounds. His recent research activities have included developing models to simulate heat and mass transport as part aerobic landfill stabilization, analysis of techniques for measuring landfill gas generation rates, and vapor-phase contaminant transport beneath landfills.

Dr. Walter holds a Ph.D. in Hydrology from the University of Arizona and M.A. in Geology from the University of Missouri-Columbia. He is a registered geologist in Arizona, California, and Wyoming, and a Registered Hydrogeologist in Washington. He is a 25-year member of the American Geophysical Union. He served as a technical advisor to the National Research Council subcommittee to review Swedish plans for

high-level nuclear waste disposal. His current work at the CNWRA is funded primarily by the Nuclear Regulatory Commission. His past work with Hydro Geo Chem was funded by a variety of industrial and governmental clients that included FMC Corporation, cities of Tucson and Phoenix, Arizona, and the Venezuelan national oil company.

Stephen Washburn

Mr. Washburn is a Principal at ENVIRON International Corporation. He has an M.S. in Chemical Engineering from the Massachusetts Institute of Technology and a B.S.E. in Chemical Engineering from Princeton University, and has over seventeen years of consulting experience in risk-based engineering and risk assessment, with special emphasis on site remediation and air-related issues. Mr. Washburn's experience at hazardous waste or industrial sites includes remedial design, remedy selection, human health and ecological risk assessment, the development of site investigation strategies, and litigation support. He has conducted risk assessments and remedy evaluations at Superfund and RCRA sites across the U.S. He is also a nationally recognized expert in the evaluation of combustion facilities, and has provided expert testimony in the areas of risk assessment, incineration, and hazardous waste management. Except for expert review activities, all of Mr. Washburn's work is performed on behalf of ENVIRON, whose clients include private sector companies, public sector agencies, and citizen's organizations. Over the past two years, Mr. Washburn's clients have included private industry (including DuPont); the federal government (including the U.S. Army); foreign governments (including the Israel Ministry of the Environment); local municipalities (including the City of Philadelphia); and financial institutions (including Deutsche Bank).

Mr. Washburn was selected by U.S. EPA to serve on the external expert peer review panels for the Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities, and for the multimedia, multi-pathway, and multiple receptor risk assessment (3MRA) model developed for the Hazardous Waste Identification Rule (HWIR). He was one of nine scientists selected by the American Society for Testing and Materials (ASTM) to provide training to state regulatory agencies and Puerto Rico on Risk-Based Corrective Action (RBCA) at petroleum hydrocarbon sites, and assisted in the development of RBCA programs in over ten states. The U.S. Army Environmental Center has designated Mr. Washburn as a Subject Matter Expert (SME) in the areas of risk assessment and decision analysis, and has assisted in the technical peer review of over a dozen active and inactive Army installations. He was also a member of the Risk Assessment Subcommittee of the Pennsylvania Science Advisory Board, which was established to encourage Brownfield development in Pennsylvania.

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July 18, 2003

Ms. Kathleen White
Designated Federal Officer
Science Advisory Board
U.S. Environmental Protection Agency (1400A)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Comments on SAB Charge Detailed in the April 11, 2003 Federal Register notice
Dear Ms. White:

The Hazardous Waste Identification Rule (HWIR) Consortium is pleased to submit these comments on the charge questions presented in the April 11, 2003 Federal Register (FR) notice (17797 FR 68) announcing the formation of a Science Advisory Board (SAB) panel to review the multimedia, multipathway, multireceptor risk assessment (3MRA) model. As part of the notice publication, the U.S. Environmental Protection Agency (EPA) proposed seven charge questions to the SAB panel in four areas: assessment methodology, 3MRA modeling system, modeling system evaluation, and modeling system documentation.

The objective of the charge questions is to provide EPA with sufficient feedback to ensure that the 3MRA model results are meaningful, accurate, and can be used in a regulatory context. These comments focus on the current EPA charge to the SAB panel (herein referred to as SAB charge) and have been prepared on behalf of a Consortium of trade associations (the HWIR Consortium) including the American Chemistry Council (ACC), the American Petroleum Institute (API), the Synthetic Organic Chemical Manufacturers Association (SOCMA), the National Council for Air and Stream Improvement (NCASI) the Utility Solid Waste Activities Group (USWAG). The HWIR Consortium members have been active participants in the review of the 3MRA model since its original publication in December 1995.

In October 2000, the HWIR Consortium submitted extensive comments to EPA on the revised 3MRA model (ARCADIS Geraghty & Miller 2000). Prior to submitting comments, the HWIR Consortium met with EPA staff from the Office of Solid Waste in November 1999 and March 2000 to fully understand the 3MRA model operation and output. Although the period for submitting comments to EPA on the 3MRA model has closed, the HWIR Consortium has continued to track the progress on 3MRA model improvements and has had an ongoing dialog with EPA on the proposed model improvements. The HWIR Consortium met with staff from the Office of Solid Waste in February 2002 and March 2003 to obtain additional information on 3MRA model improvements. In light of this involvement, the HWIR Consortium is very familiar with the 3MRA methodology, data inputs, and operation.

These comments reflect this ongoing involvement and are specifically designed to help focus the SAB charge and ensure that the SAB addresses the most important aspects of the model operation. Described below are suggestions to improve the charge as written as well as suggestions for additional charge questions.

Review of Current Charge Questions

The HWIR Consortium has reviewed the SAB charge and has several suggestions for improving the seven existing charge questions. These suggestions strive to increase the specificity of the charge questions to encourage a more thorough review. Such a review will allow EPA to be certain that the 3MRA model is operating as designed and is providing meaningful human health and ecological risk results. Specific comments on each of the charge questions are provided below.

SAB Charge Question 1

While the EPA had the assessment methodology peer reviewed prior to the development of the 3MRA modeling system, does the SAB have any additional comments about the methodology as implemented?

In charge question 1, EPA asks the SAB if they have any comments about the 3MRA assessment methodology. EPA indicates that the assessment methodology was peer reviewed prior to the development of the 3MRA modeling system; however, no information on the results of this peer review is provided in the FR notice (68 FR 17798). More importantly, the charge question as currently worded is not sufficiently specific. Instead of a single general question, the charge should focus on specific aspects of the methodology that may be of concern. Such issues might include questions related to the implementation of the Monte Carlo analysis, the statistical approach used to select the sites evaluated, or the appropriateness of using national data in a site-based assessment. Recommendations for specific questions related to the assessment methodology are presented below.

SAB Charge Questions 2a, b, and c

2a: Does the 3MRA modeling system provide a tool for performing national risk assessments that facilitates consistent use of the science and provides a mechanism for reproducing results?
2b: Does the 3MRA modeling system provide decision-makers sufficient flexibility for understanding the impacts on potential chemical exemption levels by allowing varying measures of protection based on the number of receptors and/or number of sites protected, types of human and ecological receptors, and distance?
2c: Does the 3MRA modeling system provide appropriate information for setting national risk-based regulations for the waste program?

Charge questions 2a, b, and c appropriately focus on the performance, flexibility, and regulatory value of the 3MRA model output. Of these three questions, question 2c is the most important, as it addresses the issue of whether the results of the 3MRA can and should be used to set regulatory levels. Indeed, the results of question 2c should be used to determine whether additional work with the 3MRA model continues and whether the 3MRA model can be used in any EPA programs. Although charge questions 2a and 2b are also important, the answers to questions 2a and 2b will be irrelevant if the

3MRA modeling

output cannot be used to make appropriate risk-based waste management decisions. SAB review of the model will be necessary to answer these questions.

SAB Charge Questions 3a and b

3a: Is the software development and verification testing approach implemented for the 3MRA modeling system sufficient to ensure confidence that the modeling results reflect the modeling system design?

3b: Given the thorough evaluations that EPA has implemented using the available data resources and technologies, while also recognizing the real world limitations that apply to validating the 3MRA modeling system, have we reasonably demonstrated through methodology design, peer review, quality control, sensitivity analysis, and model comparison, that the 3MRA modeling system will produce scientifically sound results of high utility and acceptance with respect to multimedia regulatory applications?

Charge questions 3a and 3b ask the SAB panel to evaluate the quality control and validation conducted for the 3MRA model. Clearly, these are critical issues as the model should not be used if the results cannot be shown to fit real world situations or if the modeling system and results are not consistent with the modeling design. A complete and thorough validation is also important because of the significant complexity and lack of transparency in the 3MRA model. Given the current operating system and 3MRA model output, it is difficult to determine whether the 3MRA model is operating as designed or more importantly, whether the results are meaningful given the significant amount of data, modules, and system processors used to generate results. To ensure that a proper validation or other quality control effort is completed, the SAB panel should consider how a validation could be completed that uses the inputs and data from all 17 modules. Although a validation of the individual modules is an important first step, it will also be necessary to validate the 3MRA model as a “whole” to ensure that the final output, based on all the individual modules working in tandem is relevant and realistic.

SAB Charge Question 4

Has the EPA made substantive progress, relative to 1995, in designing and preparing documentation for the 3MRA modeling system? Does the SAB have additional suggestions for improving the presentation of the comprehensive set of materials related to this modeling system?

Finally, charge question 4 addresses the documentation developed for the 3MRA model and its improvement since 1995. The HWIR Consortium believes that question 4 should be revised to focus only on the current documentation as a quality deliverable. Although improvements may have been made since 1995, the documentation should be transparent, concise, and of high quality in itself and not just an improvement compared to the information provided in 1995. Indeed, the documentation for the 3MRA model should meet EPA’s data quality objectives. Moreover, the SAB should also be aware that the

documentation provided for the SAB panel is not the same as the documentation released to the public in November 1999. The Office of Solid Waste has indicated that it has developed four volumes for the SAB review, none of which were available to the public when the 3MRA model was proposed (Stephen Kroner, Office of Solid Waste, personal communication).

Additional Charge Questions

The HWIR Consortium's review of the SAB charge indicates that the questions are not sufficiently specific to yield results that will help EPA improve the 3MRA model design and operation.

To increase

the efficacy of the SAB review, the HWIR Consortium suggests that the charge be expanded to include

more specific questions. These questions will ensure that the SAB review of the 3MRA model is

complete and unbiased. The charge questions presented below were developed based on specific

concerns and issues that were identified during the HWIR Consortium's review of the 3MRA model and

documentation. Each recommended charge question (in italics) is followed by a discussion of why the charge question is critical to evaluating the 3MRA model.

Charge Questions Related to Assessment Methodology

The 3MRA model uses a site-based assessment methodology that evaluates 201 individual sites using site-based, regional, and national data. The results from each of the 201 sites are then combined to determine the risk results. To evaluate this approach, EPA has asked the SAB to complete an overall evaluation of the methodology. The current charge question, however, is not sufficiently detailed to ensure that the SAB review will be complete. Instead, as described below, the SAB charge should be modified to include an evaluation of specific issues about the assessment methodology.

Additional Charge Question 1

EPA has stated that the 3MRA model has the capability of executing a Monte Carlo analysis. Has this capability been successfully implemented and integrated into the model? Does the Monte Carlo analysis define the uncertainty associated with the 3MRA model results?

The assessment methodology for the 3MRA is complex. The model describes the movement of chemicals from five types of waste management units (WMUs) through the various media, ending with exposure to human and ecological receptors. As part of this assessment methodology, EPA has indicated that the 3MRA model has the capability of running a Monte Carlo analysis. To date, however, EPA has not presented any results using Monte Carlo techniques. Indeed previous attempts to run the Monte Carlo analysis were hindered by the enormous data and resource requirements of the 3MRA model. The use of the Monte Carlo analysis should improve the 3MRA model results, in that the inputs should better characterize the range of available data. The Monte Carlo analysis is also necessary to characterize and evaluate uncertainty and variability in the model results. Therefore, it is critical that the SAB ensure that the Monte Carlo analysis has been appropriately implemented and integrated into the 3MRA assessment methodology. For example, if the Monte Carlo analysis has not been run a sufficient number of times to obtain convergence of the data distributions, data inputs from the Monte Carlo analysis may not be appropriate or consistent with the data obtained from point estimates (see Charge Question 2). If time or resource constraints prevent the Monte Carlo from being sufficiently integrated into the 3MRA model, the SAB should consider whether the results of 3MRA model can be used for regulatory purposes.

Additional Charge Question 2

Are adequate safeguards built into the 3MRA model to ensure that inappropriate combinations of assumptions and inputs are prevented? That is, could the 3MRA model combine input values

in such a

way as to consider scenarios that would not or could not exist in the real world? If so, how will these

combinations be identified and addressed prior to regulatory use?

The 3MRA model relies on site-based, regional, and national data in its calculations. For each site, the

3MRA model uses thousands of data files, possibly combining site-based and regional data in the same

pathway analysis. Moreover, the data used to calculate human and ecological risks at each site are not

readily available for review. Although some distributions and point estimates are provided to the public

in EPA's documentation, the majority of the data input calculations are selected by the 3MRA model

during each individual model run. As a result, the current assessment methodology could lead to the use

of inappropriate combinations of assumptions and input parameters. Because the public cannot readily

review the data inputs and data calculations used in the model, the SAB should evaluate the assessment

methodology to ensure that all input combinations are technically appropriate.

Additional Charge Question 3

Does the 3MRA model ensure mass balance of water between the respective modules? How can this be demonstrated?

A critical piece of the assessment methodology is the movement of constituents (leachate, water, and sediment) between modules. Although EPA has carefully examined the fate and transport of constituents, the movement of water between respective modules has not been adequately reviewed to ensure continued mass balance. As a result, EPA cannot be certain that the mass of water that is input into the system is equal to the mass that exits the system. By not understanding and quantifying the movement of water, the 3MRA may significantly overestimate predicted constituent concentrations for water-related pathways. The simplest example of this issue is the interaction between the watershed module, the vadose zone module, and the saturated zone module. Although the watershed module computes basinwide recharge that is transferred to the vadose zone module and the saturated zone module, the saturated zone module also computes groundwater flow from a regional database. The 3MRA model does not compare groundwater flow rates in the saturated zone module to recharge rates in the vadose zone module. Therefore, combinations of input parameters could be selected where the natural conveyance of the formation would be insufficient to receive the predicted recharge rates. Similar inconsistencies may exist regarding supply and demand for domestic water supply wells, as the 3MRA model does not simulate the hydraulic effects of the wells. For certain combinations of hydrogeological parameters, there may not be sufficient water or conveyance to meet the typical demand of 0.5 gallons per minute (gpm).

Additional Charge Question 4

Does the 3MRA model evaluate the appropriate level of ecological organization? Does it adequately consider population and community level ecological risks, as well as individual level risks?

The stated objective of the ecological assessment in the 3MRA model is to protect ecological populations (wildlife) and communities (soil, benthic, aquatic, plant). In the 3MRA model, however, a hazard quotient (HQ) approach is employed, wherein estimated exposures to individual organisms within a variety of receptor groups are compared to levels assumed to be without deleterious effects. Because effects to a small number of individuals rarely affect populations and communities adversely, it is unlikely that the current assessment methodology truly reflects effects at the population or community level. As a result, the ecological risk results generated using the 3MRA are expected to have limited value in predicting biologically significant adverse effects in ecological receptors. Given these concerns, the SAB should review the assessment methodology to determine whether the current approach and output are appropriate and meaningful for generating ecological risks.

Charge Questions Related To 3MRA Modeling System

Under the 3MRA modeling system section, EPA has posed three questions to the SAB that focus on the use of the 3MRA model for making regulatory decisions. As described above, the HWIR Consortium believes that charge question 2c is most critical in determining whether the 3MRA model can be used for setting exit levels under HWIR. Consequently, the HWIR Consortium believes that the SAB should more closely evaluate the human and ecological risk results to determine if these results are scientifically defensible.

Additional Charge Question 5

To what degree does the 3MRA model output accurately reflect risks to human health and the environment? How will EPA be able to document this for rulemaking purposes?

HWIR Consortium Comments Page 6

SAB Review of 3MRA

July 18, 2003

The current SAB charge evaluates whether the 3MRA model provides appropriate information for setting national risk-based regulations. However, to fully characterize whether the information used is “appropriate,” the SAB must closely evaluate the risk estimates developed for human and ecological receptors. The evaluation of human and ecological risks is a critical step in determining whether the 3MRA model is valid and whether the results can be used for regulatory purposes. Although the practice of risk assessment is by definition a method to estimate potential adverse health effects in the absence of perfect information, the regulatory importance of the 3MRA model necessitates that the risk output be subject to a high standard. At a minimum, the SAB should determine if the results likely over- or underestimate actual risks. Although the HWIR Consortium believes that the 3MRA likely overestimates potential risks, the complexity of the model and the quality of the documentation on data inputs has limited our ability to determine the extent of this overestimation. If it is not possible to determine the accuracy of the risk results based on the information provided on the 3MRA model, the SAB must determine whether regulatory application of the 3MRA model should move forward.

Additional Charge Question 6

Are there sufficient data on ecological receptors, ecological exposures, and potential ecological toxicities to use the ecological risk values in making regulatory decisions?

In the documentation for ecological receptors, EPA provides a numerical scaling system to rank the chemical-specific data availability and quality for ecological receptor groups. This information is provided to help qualify the confidence in the ecological risk results. A review of this scaling system indicates that for terrestrial systems only one chemical out of 54 had adequate information (i.e., high quality) for all receptor groups. For aquatic systems, only two chemicals had adequate information (i.e., high quality) for all receptor groups. Given the low quality of ecological data for most chemicals and receptor groups, it is critical that the SAB determine whether the available data are sufficient to allow ecological risks to be calculated and used in a regulatory context. Although data on

ecological receptors will likely always be lacking in comparison to human health concerns, if the data are not of sufficient quality or do not meet EPA's data quality objectives, the SAB should consider whether ecological receptors should be removed from the determination of chemical-specific regulatory levels.

Charge Questions Related to Modeling System Evaluation

EPA acknowledges that complete validation of the 3MRA model would demonstrate that the 3MRA model results are sufficiently predictive to be used with confidence to make regulatory decisions. However, in the absence of a complete validation, EPA has peer reviewed the individual modules and conducted numerous quality control evaluations to determine that the model is operating as designed. Such a validation and quality control effort is important towards understanding how well the 3MRA model operates; however, the SAB should also evaluate the validity of the model results holistically (i.e., all 17 modules are working together).

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Additional Charge Question 7

Absent validation of the complete model, is it possible to ensure that the 17 modules work together, that data transfer between modules is appropriate, and that the model generates accurate and meaningful risk results?

The 3MRA model has been peer reviewed several times; however, in each case, the peer review just focused on one individual module. As a result, a peer review or validation of all 17 modules integrated together has not been completed. Such a complete validation is necessary to ensure that the individual modules have been linked correctly and that data transfer between modules is appropriate. In other words, there is no information available that indicates that the whole 3MRA model works as well as the individual parts. The HWIR Consortium has identified several instances where data interaction between modules is questionable. For example, data generated in the vadose zone module appears to be very detailed; however, this information is then distilled down to a single average value as input into the saturated zone module. Although a comprehensive review of all 17 modules used in the 3MRA model maybe outside the scope of the SAB review, the SAB should determine whether such a review is necessary before the 3MRA model can be used for regulatory decision-making.

Additional Charge Question 8

What are the minimum validation requirements? Have these been met? Is the level of Quality Assurance/Quality Control (QA/QC) satisfactory?

EPA has asked the SAB to determine if the validation for the 3MRA model is reasonable, given the limitations associated with validating a multimedia, multipathway model. However, before SAB can determine that the validation is sufficient, they must first independently define minimum validation requirements. Many models are validated based on how well the model predicts real world or sitespecific results (e.g., within a certain percentage, defined *a priori*). These validation requirements

would define the approach and level of validation required to provide confidence in the 3MRA model results, and would define whether the current validation effort meets these requirements. Such an approach would ensure that the model validation meets typical industry standards or ensure that the 3MRA model continues to undergo validation before being used in a regulatory setting.

Charge Questions Related to 3MRA Modeling System Documentation

The documentation associated with the 3MRA model is voluminous and covers all modules used in the model, as well as the overall assessment methodology approach. Although EPA has updated the 3MRA model documentation for the SAB review, it is not clear whether the documentation provides sufficient technical information to allow a complete understanding of the model operation. In particular, the HWIR Consortium is concerned about the amount of information provided on the Monte Carlo data and analysis. As stated below, the SAB should review the documentation to ensure that all inputs and distributions used in the Monte Carlo analysis are presented.

Additional Charge Question 9

Has EPA sufficiently documented the Monte Carlo analysis to allow a complete review of all data inputs?

Understanding the data used in the 3MRA model is critical to ensuring that the model results are meaningful. Because the Monte Carlo analysis is a critical part of the 3MRA model operation, all data inputs should be sufficiently documented. Such documentation should include a description of and supporting data for the distributions selected. Previous documentation provided by EPA, however, did not contain a sufficient level of detail for many modules. For example, EPA (1999a) presented the input

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and output variable names and descriptions for the farm food chain, but the values used in the model were not specified. Likewise, for the vadose zone, EPA (1999b) presented the input and output variable names, but not the actual data. Without such data, it is difficult to determine if the data distributions used to calculate risks are appropriate for each variable.

Charge Questions Related to Data Quality, Data Usability, and Data Inputs

EPA's current charge questions to the SAB focus on the modeling system approach, usability, and documentation. However, a critical factor omitted from the SAB charge is an evaluation of the data inputs and data usability. Like any risk assessment or exposure model, the quality of the output reflects the quality of the data input. As a result, the SAB charge should also include questions related to data quality and data usability. As defined in EPA's (2002) *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*, the information generated by the 3MRA model should be considered influential information. It is therefore subject to a higher degree of quality compared to other information that may not have a

substantial impact on public policies. Given the importance of data in the 3MRA model, the HWIR

Consortium recommends that the following questions be added to the SAB charge.

Additional Charge Question 10

Do the assumptions related to waste management practices, such as operational lifetimes and the

presence of liners and controls for runoff and erosion accurately reflect current conditions?

Should more

current site-specific data on the 201 sites be incorporated into the model?

The 3MRA model currently uses the results of the 1985 Subtitle D survey to evaluate locations,

dimensions, and waste volumes for landfills, land application units, and surface impoundments. As

acknowledged by EPA, these data are more than 15 years old and are not expected to represent current

practices or adequately describe current waste management unit characteristics. Over the last 15 years,

management practices used for nonhazardous waste disposal have changed significantly, as both states

and EPA have enacted more regulations for waste disposal and management. As a result, the HWIR

Consortium is concerned that the data used to describe the 201 sites modeled in the 3MRA model are

outdated, likely erroneous, and of significantly less quality than required by EPA (2002). In several

instances throughout the 1985 survey, the authors express concern about the quality of these data. For

example, Schroeder, Clickner, et al. (1987) state that “estimates of capacity and surface area have high

sampling error” (p. 3-3), that “comments indicated that a number of estimates, particularly for capacity,

may not be very accurate” (p. 3-8), that “a number of respondents were unsure about quantity estimates

that they provided” (p. 3-7), and that “sampling errors for the national estimates of capacity and surface

area tended to be unusually high” (p. 3-3). These statements indicate that the SAB should conduct a

critical review of the WMU data generated from the 1985 survey. Without this review EPA cannot

determine that the data reflect present and future locations of WMUs or current waste management

practices.

Additional Charge Question 11

Is the quality of data used in the 3MRA model sufficient to ensure that the model results are accurate and

realistic? Will the data needed to run the model meet the new data quality guidelines?

As stated above, the HWIR Consortium is concerned that the data used in the 3MRA model is not of

sufficient quality to meet the guidelines specified by EPA (2002) for influential risk assessments. Indeed,

the quality of the data used in the 3MRA model is a key determining factor in the quality of the 3MRA

model results. Although an extensive review of all the data used in the 3MRA model may be too large a

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task for the SAB panel, specific modules or data should be identified for detailed review and evaluation.

Examples of data to be reviewed could include the data on WMUs (see Charge Question 10), data on

ecological exposures and toxicities, data used in the vadose zone and saturated zone modules

for groundwater movement, and data used to estimate runoff and surface erosion. A focused review of data used in individual modules will help ensure that the data inputs are of sufficient quality to allow the results to be used in making regulatory decisions.

Conclusions

The HWIR Consortium appreciates the opportunity to participate in the SAB review process for the 3MRA model. We hope that the SAB review will address the issues that are important to the public and regulated community. Although EPA has posed some critical questions to the SAB, the HWIR

Consortium believes that the current charge questions should include more details to encourage a thorough review of the 3MRA model. In particular, the SAB review should place an added emphasis on determining the accuracy of the human health and ecological risk results and validating the integration of all 17 modules used in the 3MRA model. These two issues are critically important as confidence in the 3MRA model can only be obtained if the model operation and output can be shown to meet a high technical standard.

Please feel free to contact any of the members of the HWIR Consortium if you have any questions regarding our comments or suggested charge questions.

Sincerely,

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National Council for Air and Stream Improvement

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Synthetic Organic Chemical Manufacturers Association

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